COMBI 500

ELECTROTHERAPY ULTRASOUND LASER UNIT

OPERATING INSTRUCTIONS

Your supplier is:

The COMBI 500 is made in Belgium by ***GymnaUniphy***

At the beginning of these Operating Instructions you will find an exploded view of the Combi 500 and its accessories.
The numbers on the drawings correspond to the numbers in these Operating Instructions.
We advise you to go through these Operating Instructions, while you get familiar with your new Combi 500.

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2 SAFETY REGULATIONS

2.1 Electrical safety

The Combi 500 may only be used in a room equipped with conveniences meeting the legal requirements in force. The Combi 500 must be connected to a properly grounded wall plug that meets the locally applicable requirements for medical rooms.

2.2 Explosion prevention

Do not operate the Combi 500 in a room where inflammable gases or fumes might be present. Switch off the device before starting to disinfect or decontaminate the room where it is placed, for instance.

2.3 Operational safety

2.3.1 Operational safety - Generalities

- The Combi 500 is suitable for continuous use.
- Using the Combi 500 together with a short wave or microwave appliance might have an influence on the output of the Combi 500.
- Using the Combi 500 simultaneously with a high-frequency surgery apparatus might lead to burns under the electro-stimulating electrodes.
- Patients with electrical implants (e.g. pacemaker) may only be treated after gaining medical advice.
- Do not operate the Combi 500 in a wet room.
- Do not disinfect or sterilize the Combi 500.
- Regularly check if the insulation of the electrode cables and the electrodes themselves is still intact. If this is not the case, replace the wiring and/or the electrodes.
- An appropriate and safe use of the Combi 500 is only guaranteed if one uses the standard and/or optional accessories, mentioned in these Operating Instructions (see *Chapter 16: ACCESSORIES)*
- In order to warrant the safety of the Combi 500 for a longer period of time, we advise you to have the unit itself and the accessories checked at least once a year during a safety and technical control (*refer also to paragraph 2.7).*
- The safety standards for electrotherapy recommend not exceeding the current density of 2.0 mA_{rms}/cm^2. During iontophoresis treatments, however, we recommend not to exceed the current density of 0.2 mA_{rms}/cm^2. Overstepping might cause skin irritation and burns.
- An optimal treatment starts with an examination of the patient. Based upon these findings a treatment plan and treatment objectives can be established. One has to control these plans and objectives very thoroughly during the treatment itself. In that way, possible risks linked to the treatment can be minimized.
- Always keep these Operating Instructions in the vicinity of the appliance.

2.3.2 Operational safety – while using lasers

- The radiation of a laser probe can cause a physiological effect. The laser beam is invisible; the use of the laser by unauthorized persons or a longer exposure to the radiation might cause injuries. That is the reason why any non-therapeutic exposure should be avoided.
- Never look into the laser probe during a laser therapy, and never point the probe to somebody else's eyes (e.g. the patient).
- The therapist as well as the patient must wear laser spectacles all the time. GymnaUniphy furnishes 2 laser spectacles together with each laser probe [52]. These spectacles have an attenuating effect of more than 100. It is still possible to see the controls and lights of the laser probe through the glasses. One may also use laser spectacles having at least the following characteristics: I 100 – 1000 L2.
- Do not hold the laser probe in the vicinity of inflammable materials or liquids during the treatment.
- The Combi 500 is equipped with an ignition lock to start the laser emission. In the event that the Combi 500 is not used for laser therapeutical purposes, this locking key is to be set in the "OFF" position (= horizontal). To avoid inexpert use when the Combi 500 unit is not under the supervision of the therapists, it is strongly advised to switch the locking key to "OFF" and to extract the key from the unit.
- The application of checks, modifications, operations or procedures deviating from those mentioned in these Operating Instructions can lead to irresponsible exposures to laser radiations.
- The warning symbol Laser must be affixed at the entrance of the room where the laser will be operated.

2.4 Transportation and storage

The way it is packed up in its original wrapping, the Combi 500 unit is suitable for transportation and storage (for a maximum period of 15 weeks) within the following limits:

- Temperature from –20 °C to +60 °C;
- Relative humidity from 10 % - 100 %, inclusive condensation;
- atmospheric pressure from 500 hPa - 1060 hPa.

2.5 Use of the Combi 500

The Combi 500 was exclusively designed to administer the following therapies: electrotherapy, ultrasound therapy, combined therapy and laser therapy. The use of the unit is strictly limited to authorised and expert personnel (trained in the application of the therapies mentioned above). It is mandatory to follow the directives in these Operating Instructions as closely as possible.

NOTE:
The ambient temperature for operating the Combi 500 is between +10 °C and +40 °C.

2.6 Medical Device Directive

The Combi 500 meets the most recent adapted essential requirements of the Medical Device Directive of the European Commission (93/42/CEE).

See Chapter 12: INTERFERENCES, WARRANTY, LIABILITY, SERVICE concerning the liability of the manufacturer.

2.7 Technical Control

The Medical Device Directive of the European Commission (93/42/CEE) makes it mandatory for the user of the Combi 500 to have the unit checked during a safety and technical control at least once a year, and especially after all repairs. This is in accordance with the directive mentioned above.

This safety and technical control consists of:

1. a visual control,
2. a safety check,
3. the examination of all the operating functions and the measurement of the output signals,
4. the control of the alarm functions,
5. the measurement of the over current protective device,
6. the measurement of the ground leakage current and the patient leakage current, in accordance with the EN 60601 safety standard,
7. the calibration of the laser detector,
8. the examination of the output of the laser probes.

The results of these checks must be recorded in the service logbook.
The service logbook can be found in the back of the “Treatment Guide” under the tab SERVICE.

NOTE:
Safety and technical inspections may only be conducted by a recognized safety inspection body or by a technician approved and qualified as thus by GymnaUniphy.

2.7.1 Inspection interval

The unit is designed in such a way that an annual inspection is sufficient. In the event that the local legislation in the user’s country (or his insurer) imposes shorter intervals, one has to comply with them.

2.7.2

Inspection results

The inspection has been carried out completely when al the topics of the annexed inspection report (see tab SERVICE in the Treatment Guide) have been checked. Abnormalities have to be adjusted (or repaired if necessary) before using the unit again. The intention is that the user makes a certain number of copies of the inspection report, so that there are a sufficient number of copies available for several controls.

NOTE:
Technicians authorized to do so by GymnaUniphy may only carry out repairs. Contact your local Gymna dealer to know their addresses.

3 INSTALLATION

3.1 Introduction

At the beginning of these Operating Instructions you will find an exploded view of the Combi 500 and its accessories. The numbers in these Operating Instructions correspond to the numbers on the drawings.

3.2 On receipt of your Combi 500 unit

Check if the Combi 500 was not damaged during the shipment.
Also check if the accessories are intact and complete.
(See Chapter 16: ACCESSORIES).
In the event of any damage and/or malfunction notify your supplier immediately (= within 3 working days after the delivery) by means of telephone, fax, e-mail or letter.
In the case of damage, the unit may not be operated.

Mains voltage:
The Combi 500 is suitable for a rated mains voltage of 110, 115, 127, 220, 230 or 240 Volt AC / 50-60 Hz. Check if the mains voltage matches the voltage on your own circuitry and electricity supply system. The mains voltage of the unit can be easily adjusted by means of a coin through the mains voltage selector switch [33] (on the bottom of the unit).

3.3 Connecting and starting

- Carefully check the mains voltage *(see paragraph 3.2)* before connecting the plug to the power point (input mains [29] at the backside of the appliance).
- Place the Combi 500 horizontally and stable.
- The ventilation opening [31] may not be covered.
- No objects may be put on the Combi 500.
- Do not let any liquid drop over the Combi 500.
- Do not put the Combi 500 in direct sunlight and do not put it above a heat source.

If there is no text on the display after switching it on, adjust the contrast by slightly turning the contrast control [34] (at the backside of the unit).

3.4 Language selection

- There is a choice between four languages: English, German, French and Dutch.
- The setting of a language is only possible if there is no treatment in progress.
- One has to proceed as follows: on the display Start menu, the key Return must be pressed and held during 3 seconds.
- Select the language (Green Keys).
- A selected language can be changed with the aid of the keys and .

3.5 Hooking up accessories on the connectors

3.5.1 Electrotherapy-connectors [20] [21]

1) The double-wired electrode cable [37] has at each output a rubber electrode [38] or an adhering electrode [43] (the latter have to be connected by means of an adaptor [42]).

ATTENTION:
- When using currents with a galvanic component, such as galvanic and diadynamic currents, pulsating rectangular and triangular currents, the application of adhering electrodes is strongly discouraged because of the danger of cauterisation and etching effects *(see also Chapter 14: SPECIFICATIONS)*

2) One vaginal or anal stimulating probe, to be coupled directly to the electrotherapy connectors [20] [21].

3) One rectal stimulating probe, to be connected through one cable of the double-wired electrode cable [37].

ATTENTION:
- Electrotherapy on the display at channel A = Output signal on the A output [20].
- Electrotherapy on the display at channel B = Output signal on the B output [21].

3.5.1.1 Vaginal, anal or rectal stimulating probes

For the treatment of e.g. several incontinence problems.

The Combi 500 recognizes the vaginal and the anal probes (= probes equipped with a DIN-connector). As soon as one of these probes is connected, the unit will only select alternating currents (TENS, NMES, and bipolar interferential currents) with a Constant Voltage (CV) setting. All other current shapes may not be selected at that time. *(See also Chapter 14: SPECIFICATIONS.)*

WARNING:
The Combi 500 DOES NOT RECOGNIZE THE RECTAL PROBE and thus allows in principle the use of all sorts of current shapes whenever connected.
In order to avoid unpleasant sensations and cauterisation or etching **we advice to utilize exclusively selected Constant Voltage settings** (TENS, NMES, and bipolar intermediate frequency currents) **when using a rectal probe**

See paragraph 7.7 for more information about the Constant Voltage.

3.5.2 The ultrasound connectors [22] [23]

Connect the multi-frequent ultrasound (US) head(s) [45] to an arbitrary US-connector [22] [23].
The Combi 500 automatically selects the US head that was connected last.
The lights on the US heads indicate which US head has been selected.
(*see also paragraph 6.12.6)*

3.5.3 The laser-connector [24]

Either the Mono-probe [48] (model 543) or the quadruple probe [53] (model 545) can be connected.

OPERATIONAL SAFETY OF THE LASER:

- The radiation of a laser probe can cause a physiological effect. The laser beam is invisible; the use of the laser by unauthorized persons or a longer exposure to the radiation might cause injuries. That is the reason why any non-therapeutic exposure should be avoided.
- Never look into the laser probe during a laser therapy, and never point the probe to somebody else's eyes (e.g. the patient).
- The therapist as well as the patient must wear laser spectacles all the time. GymnaUniphy furnishes 2 laser spectacles together with each laser probe [52]. These spectacles have an attenuating effect of more than 100. It is still possible to see the controls and lights of the laser probe through the glasses. One may also use laser spectacles having at least the following characteristics: I 100 – 1000 L2.
- Do not hold the laser probe in the vicinity of inflammable materials or liquids during the treatment.
- The Combi 500 is equipped with an ignition lock to start the laser emission. In the event that the Combi 500 is not used for laser therapeutical purposes, this locking key is to be set in the "OFF" position (= horizontal). To avoid inexpert use when the Combi 500 unit is not under the supervision of the therapists, it is strongly advised to switch the locking key to "OFF" and to extract the key from the unit.
- The application of checks, modifications, operations or procedures deviating from those mentioned in these Operating Instructions can lead to irresponsible exposures to laser radiations.
- The warning symbol Laser must be affixed at the entrance of the room where the laser will be operated.

3.6 Functional test

- During production the Combi 500 is thoroughly checked for electrical safety.
- When switching on the Combi 500, the microprocessor is performing an extensive test In order to verify the correct functioning of the unit.
- Check if the display is functioning properly. If this is not the case, do not continue to use the device and inform the repair services of your local Gymna dealer.

3.7 New owner

The 'Medical Device Directive' of the European Commission (93/42/CEE) prescribes that this type of medical equipment should be traceable. That is why we are kindly requesting every (new) owner to urgently give to the local Gymna dealer the name, address and other relevant data of the new owner, of the Combi 500 as well as its specific accessories US-heads and laser probes >> important: these devices have their own serial number.

3.8 Liquidation

Turn in the Combi 500 and all its accessories to a company specialised in the liquidation and recycling of electronic products and components. In those countries where there is a "take back" option in force, please contact your local Gymna dealer.

In the event that the owner is willing to destroy the unit himself or if he is willing to take the responsibility for doing this, the following information concerning environmental consequences might be interesting.

The parts of the Combi 500 can be classified into three categories:

1) The basic units, wiring, electrodes, US heads, laser probes and the Treatment Guide are to be considered as electronic or as small chemical waste. They consist of, amongst others, lead, tin, copper, iron, a diversity of other metals and several man-made materials. In most of the countries this waste is classified as "small chemical waste". Refer to the national regulations in force in your country for that matter.
2) Sponges, sponge sachets and gels only hold organic material and therefore do not need any special attention.
3) Packaging materials and the Operating instructions can be recycled. Depending on the local organization of the waste disposal, they have to be turned in at dedicated collecting points or they have to be evacuated with the regular dustman/ garbage man.

NOTE:
In most of the countries it is not allowed any more to dispose off these kinds of appliances through the regular garbage disposal channels (because of the man-made plastics and of the electronic components).

4 CONTROLS

4.1 Introduction

At the beginning of these Operating Instructions you will find an exploded view of the unit and its standard accessories. The figures below correspond to those on that plan.

4.2 Controls, connectors, standard accessories

1. Display, screen.
2. Selecting a Menu or a Parameter (green keys).
3. Increasing and setting of a Parameter; browsing in the lists.
4. Decreasing and setting of a Parameter; browsing in the lists.
5. Key for the Channel selection between A or B.
6. Intensity control for Channel A.
7. Intensity control for Channel B.
8. Key Menu Electrotherapy.
9. Key Start Menu.
10. Key memory.
11. Key Ultrasound.
12. Key Combined therapy.
13. Key Laser therapy.
14. Key Help.
15. Key Return.
16. Key Enter
17. Key Pause.
18. Key Stop.
19. Testing eye Laser emission.
20. Connector Electrotherapy - Channel A.
21. Connector Electrotherapy – Channel B.
22. Connector Multi-frequent Ultrasound head 1.
23. Connector Multi-frequent Ultrasound head 2.
24. Connector Laser probe.
25. Indicator lights (yellow) Current passage per channel.
26. Locking key Laser.
27. Mains voltage switch.
28. Fuse holder.
29. Input mains voltage.
30. Label with data of the unit.
31. Ventilation opening.
32. Connector RS 232 for service purposes.
33. Selection Mains voltage (at the bottom of the unit).
34. Contrast adjustment of the screen.
35. Indicator light Stand-by (yellow).
36. Mains voltage cable.
37. Two-wire electrode cable.
38. Rubber electrodes.
39. Electrode sachets, alvose.
40. Elastic fixations.

41. Test plug V/V - 4mm.
42. Adapter cables 4 mm to 2 mm to connect adhering electrodes.
43. Adhering electrodes.
44. Stimulating electrode with sponge.
45. Treatment head Ultrasound 4 cm^2 (multi-frequency).
46. Contact gel - 150 ml.
47. Treatment Guide with Operating Instructions
48. Mono-probe Laser.
49. On/Off push button Laser probe.
50. Green LED: Laser probe.
51. Yellow LED: Laser probe.
52. Laser protecting glasses I 100 – 1000 L2 (TX = 0.01 @ 904 nm)
53. Quadruple probe Laser.
54. On/Off push button Laser probe
55. Green LED: Laser probe
56. Yellow LED: Laser probe
57. Label Quadruple probe Laser (type 545).
58. Label Mono probe Laser (type 543).

RECOMMENDATION:
CAREFULLY preserve the parts you do not use immediately (e.g. probe holder, bolts, socket head wrench, key switch of the laser, set of spare fuses, …).

5 SELECTION OF A TREATMENT

5.1 Different therapeutic possibilities - generalities

The Combi 500 is equipped with two channels separated from each other and serving for electrotherapeutic purposes, one channel for ultrasound and one channel for laser applications.

These channels can be adjusted independently from each other, this means that one can treat two different indications simultaneously and administer two different therapies.

A concise overview of the therapeutic possibilities that can be administered simultaneously is given below.

Channel A	**Channel B**
Electrotherapy	Electrotherapy
Electrotherapy	Ultrasound therapy
Electrotherapy	Laser therapy
Ultrasound therapy	Electrotherapy
Laser therapy	Electrotherapy
Laser therapy	Ultrasound therapy
Ultrasound therapy	Laser therapy

Exceptional: not possible

Electrotherapy	Laser therapy 545 probe

5.2 Start menu.

There are three different methods to adjust the unit.

1. By means of the Start menu

Via the Start menu the treatment possibilities are represented step by step.
These possibilities are the following: Objectives
Indication list
Program number
Diagnostic programs

2. By means of direct selection of the Therapeutic method.

See paragraph 5.3.

3. Recall the own designed programs by means of the treatment memory.

See Chapter 9 : TREATMENT MEMORY.

5.3 Therapeutic keys

The Therapeutic keys are at the left hand side of the screen and they constitute a ***rapid way to come to a treatment method.***

Key Start menu
Objectives, Indication list, Program number, Diagnostic programs and the list with Contra-indications are now available.

Key Menu Electrotherapy
The current shapes can be directly selected.

Key Ultrasound therapy
The treatment display appears now immediately.

Key Combined therapy
The current shapes for the Combined therapy can be directly selected.

Key Laser therapy
The treatment method appears immediately.

Key Memory
Store the program, open it or erase it.

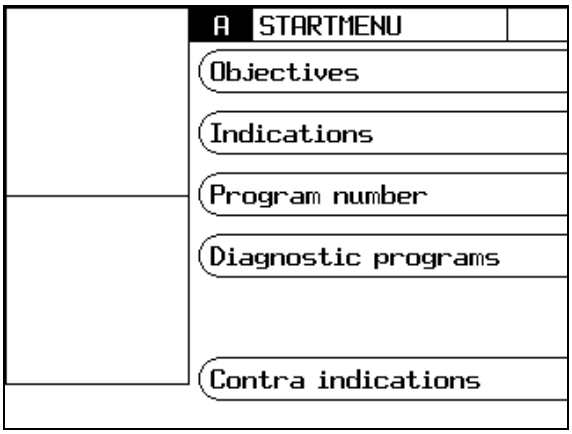
The different possibilities are described in detail in the following paragraphs.

See Chapter 6: GENERAL OPERATING INSTRUCTIONS for more details about the operation of the Combi 500 unit.

5.4 Selection of a treatment method by means of OBJECTIVES

The Start menu appears automatically the moment the unit is switched on.

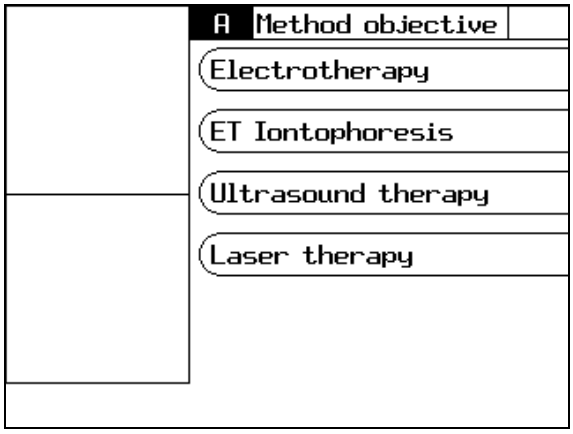
The Start menu also appears when pushing the Start menu key.
In the Start menu select Objectives in order to select a specific therapy method.



Select Objectives

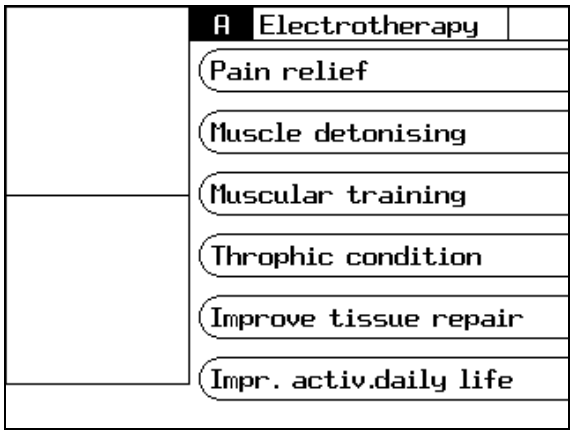
5.4.1 *Objective Electrotherapy, example of a selection*

Due to the fact that the objectives of the four proposed therapeutic methods Electrotherapy, Iontophoresis, Ultrasound therapy or Laser therapy often are essentially different from each other, one gets the choice out of a list of therapeutic methods first of all.



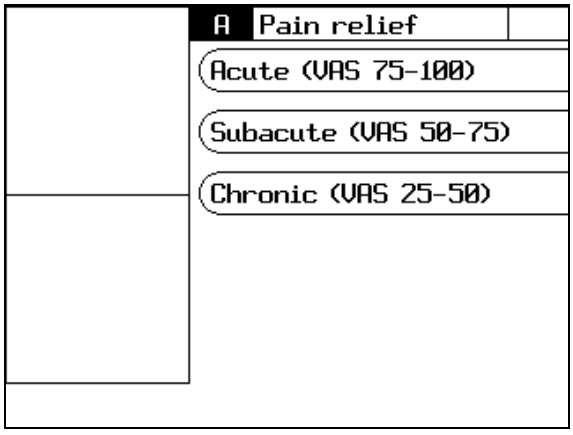
Select Electrotherapy

Subsequently a list with Objectives for Electrotherapy follows.

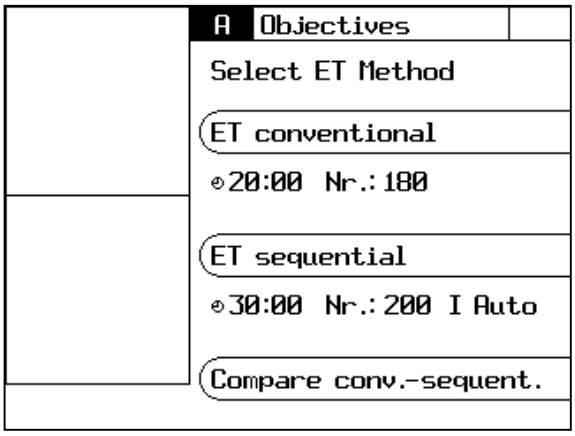


Select Pain relief

Followed by a list of specifications



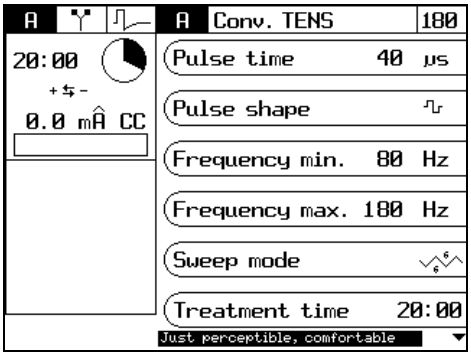
Select Acute

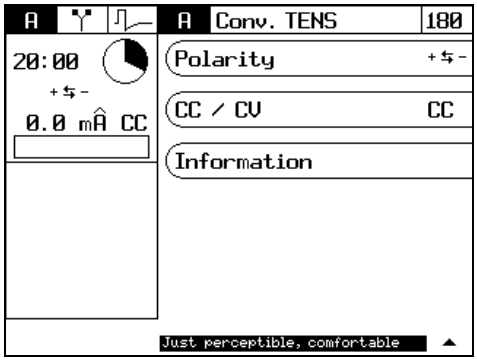


Select ET Conventional

See paragraph 7.6 for more information about the difference between ET Conventional and ET Sequential.

Subsequently a window appears with the recommended Therapy method (upper line on the screen), together with the parameters (see both displays below) and the advice for the intensity (lower line of the screen).





When a parameter is selected, one is able to modify the value of the selected parameter by using the keys and . The advice about the intensity disappears for a while and instead one sees the adjusting range of the selected parameter.

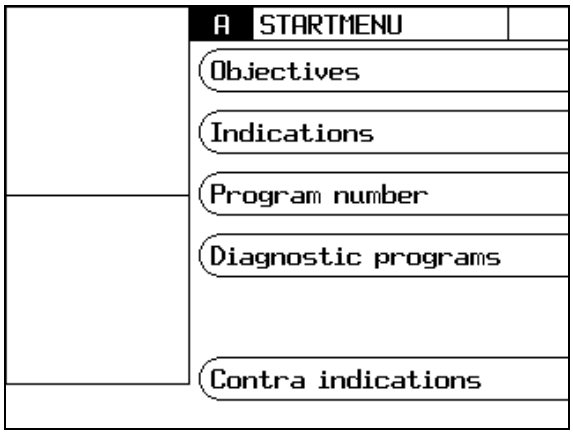
5.4.2

Objective Laser therapy, example of a selection

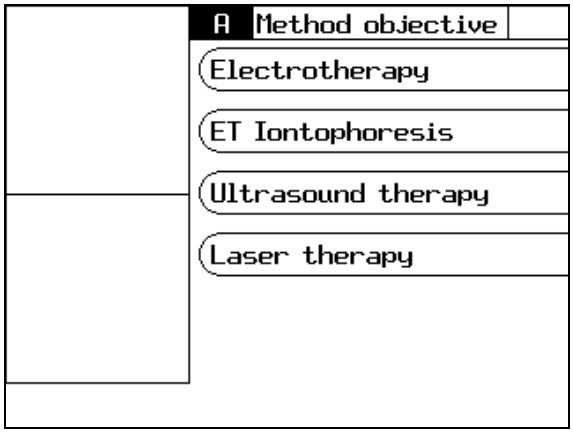
The Start menu appears automatically when the unit is switched on.

The Start menu also appears when pushing the key Start menu

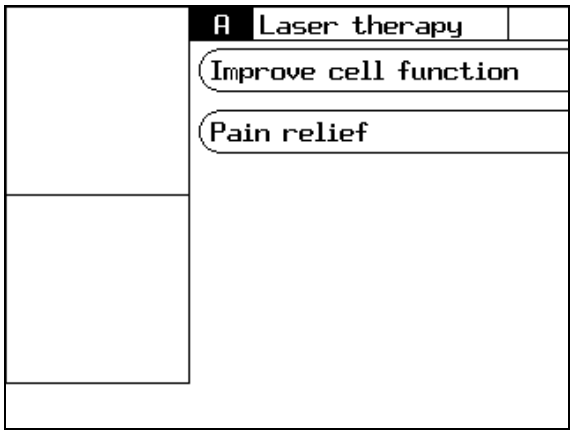
Select Objectives out of the Start menu in order to select a specific Therapy method.



Select Objectives

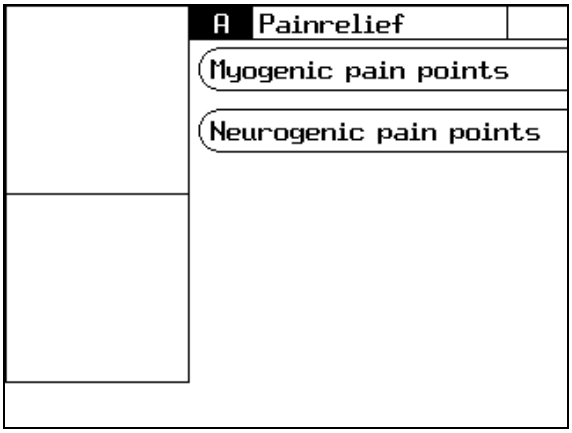


Select Laser therapy



Select Pain relief

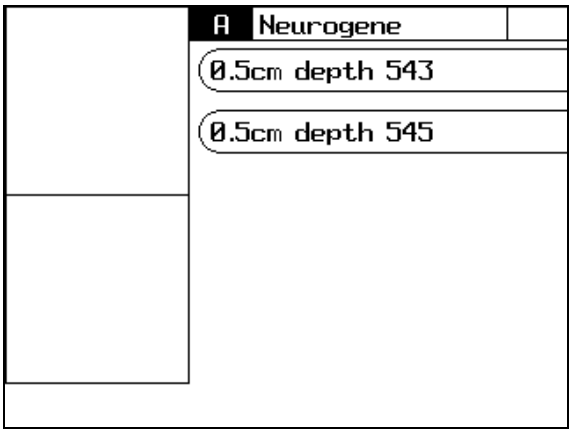
Subsequently one can make a choice between Myogene and Neurogene pain points.



Select Neurogenic pain points

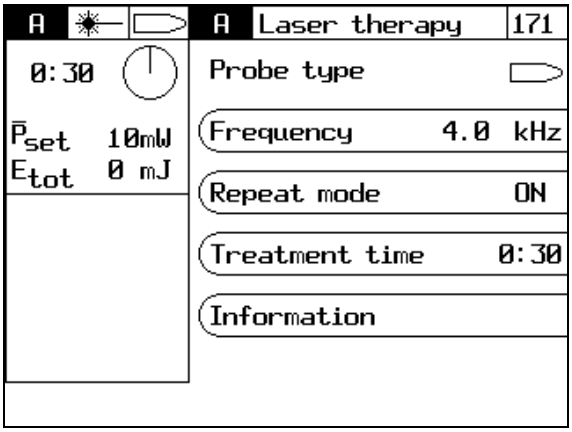
The screen (see below) now proposes either the Mono probe [48] (type 543) or the Quadruple probe [53] (type 545) for the treatment.

Make a selection of the type of probe and connect the correct probe (when connecting the wrong probe, a message will appear in the lower part of the screen).



Select Mono probe - type 543

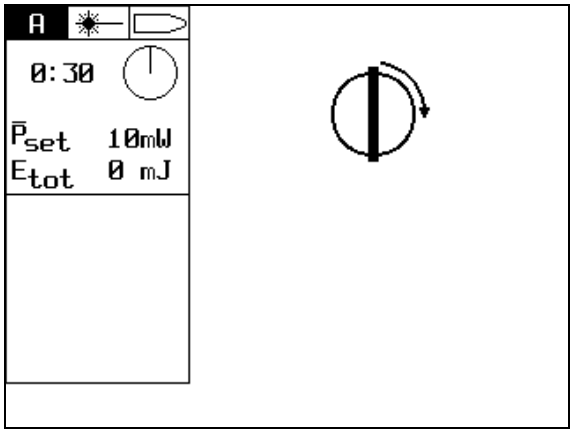
The parameter Probe type is never outlined (see below). This means that this parameter cannot be selected. The Combi 500 detects the connected probe automatically.



OPERATIONAL SAFETY OF THE LASER

- The radiation of a laser probe can cause a physiological effect. The laser beam is invisible; the use of the laser by unauthorized persons or a longer exposure to the radiation might cause injuries. That is the reason why any non-therapeutic exposure should be avoided.
- Never look into the laser probe during a laser therapy, and never point the probe to somebody else's eyes (e.g. the patient).
- The therapist as well as the patient must wear laser spectacles all the time. GymnaUniphy furnishes 2 laser spectacles together with each laser probe [52]. These spectacles have an attenuating effect of more than 100. It is still possible to see the controls and lights of the laser probe through the glasses. One may also use laser spectacles having at least the following characteristics: I 100 – 1000 L2.
- Do not hold the laser probe in the vicinity of inflammable materials or liquids during the treatment.
- The Combi 500 is equipped with an ignition lock to start the laser emission. In the event that the Combi 500 is not used for laser therapeutic purposes, this locking key is to be set in the "OFF" position (= horizontal). To avoid inexpert use when the Combi 500 unit is not under the supervision of the therapists, it is strongly advised to switch the locking key to "OFF" and to extract the key from the unit.
- The application of checks, modifications, operations or procedures deviating from those mentioned in these Operating Instructions can lead to irresponsible exposures to laser radiations.
- The warning symbol Laser must be affixed at the entrance of the room where the laser will be operated.

Introduce the locking key into the contact, or in the event that the key is in the wrong position, the following message appears on the screen.



5.4.3 *Objective ET Iontophoresis or Ultrasound therapy, example of a selection*

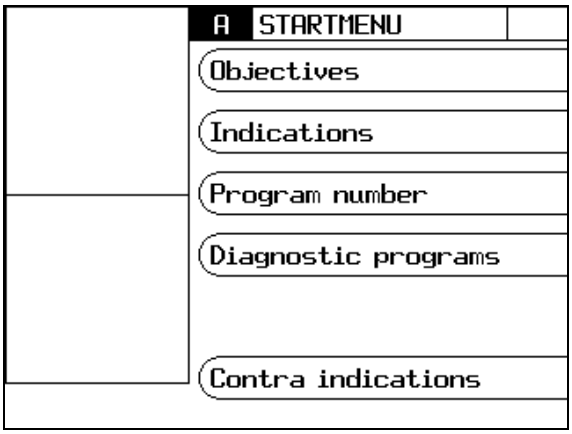
In order to select the treatment method ET Iontophoresis or Ultrasound therapy through Objectives, one can proceed in the same manner as was done in the representations above 'Objectives > Electrotherapy' (*see paragraph 5.4.1)* and 'Objectives > Laser therapy' *(see paragraph 5.4.2)*

5.5 Selecting a treatment method through INDICATION LIST

The Start menu appears automatically when the unit is switched on.

The Start menu also appears when pushing the key Start menu .

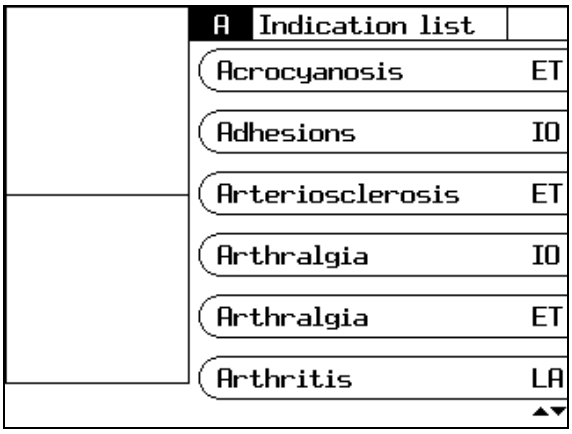
Out of the Start menu, one selects Indication list (see below).



Select Indications

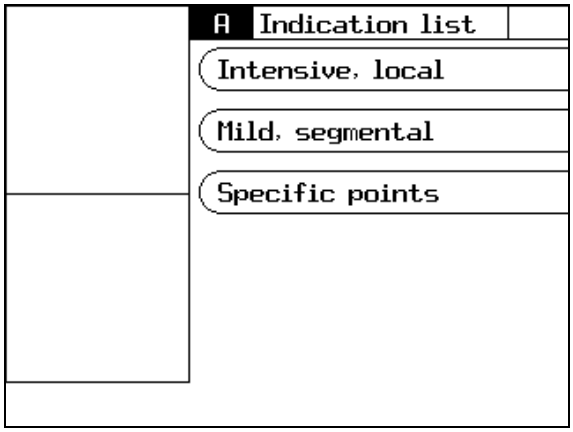
An alphabetical list is displayed showing all the Indications on screen.
Behind a specific Indication, there is an abbreviation of the advised Therapy method,
That is to say ET = Electrotherapy, IO = Iontophoresis, LA = Laser therapy, US = Ultrasound therapy, CO = Combined therapy.

It is possible to browse through the indications by using the keys and .



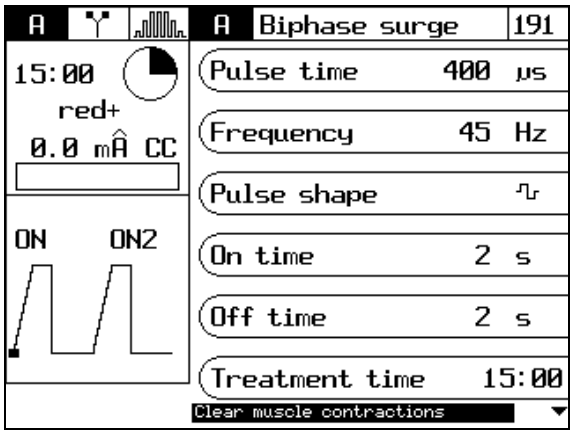
Select Arteriosclerosis

After having selected one of the Indications one can either further specify it (e.g. acute), or choose from the desired therapy methods (see below).



Select Intensive, local

The display shows the recommended Therapy method, together with the parameters and the advice for the intensity, where both are tailored to the Indication.



See paragraph 6.6 for more explanation about the modification of a parameter.

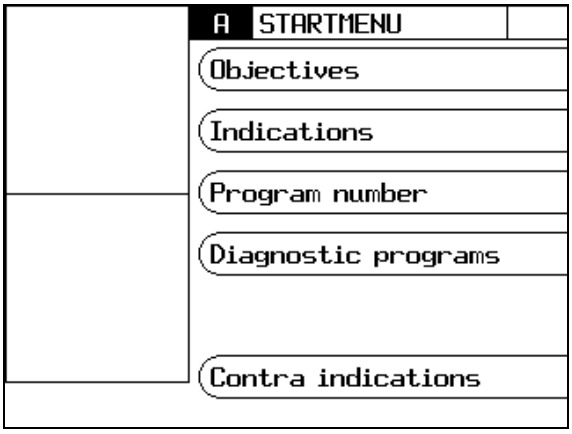
5.6 Selecting a treatment method through a PROGRAM-NUMBER

The Start menu appears automatically when the unit is switched on.

The Start menu also appears when pushing the key Start menu

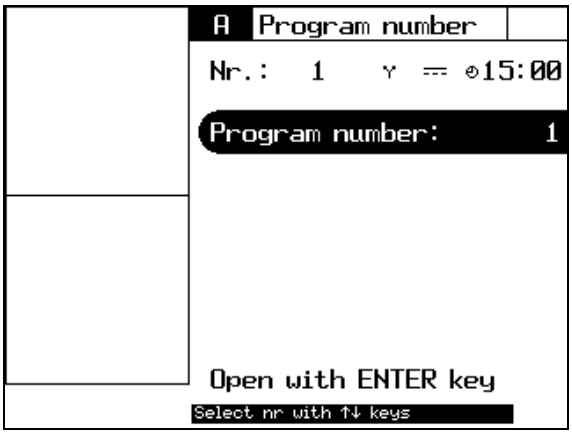
All treatment programs have their own program number.
Out of the Start menu one selects a Program number (see below).

This is the quickest way to enter into the desired program.



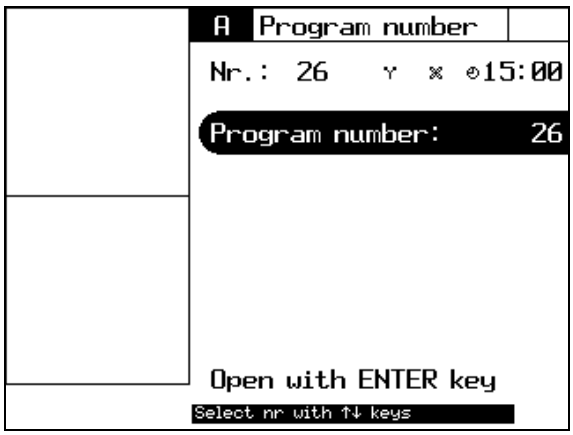
Select Program number

The second line (see below) gives concise information about the selected program. Select the correct program number through the keys and



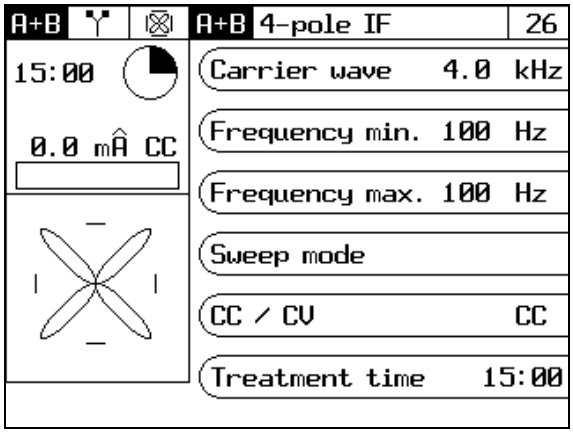
Push the key

When the desired number is reached, one pushes the key Enter



Press the Enter key

The parameter display appears immediately.



See paragraph 6.6 for more explanation about the modification of a parameter.

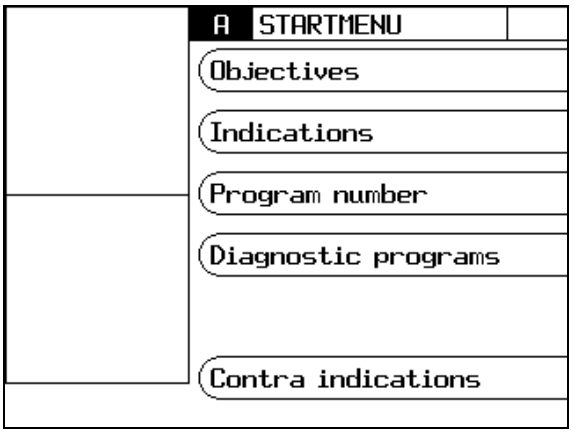
5.7 Selecting programs for DIAGNOSTICS

A certain number of current shapes can be applied diagnostically.
Hereby different possibilities are opened enabling the therapists to determine in a simple way the Rheobase and the Chronaxie or dressing up an S-D curve.
Through a certain number of programs one can localize and treat pain points.

The Start menu appears automatically when the unit is switched on.

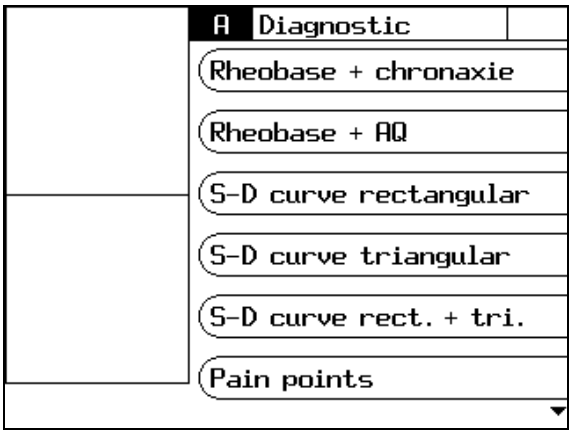
The Start menu also appears when pushing the key Start menu

In order to determine for instance the Rheobase and the Chronaxie, one starts in the Start menu and one chooses Diagnostic programs.



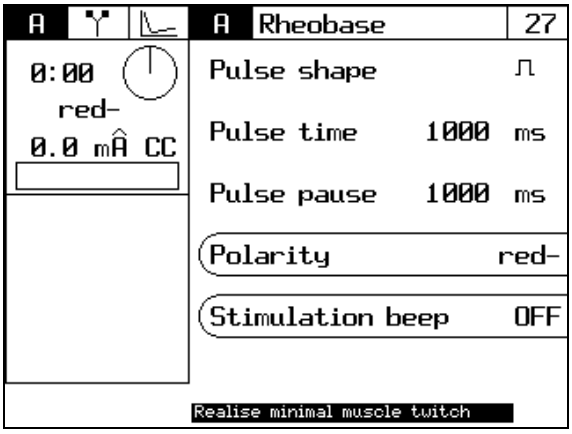
Select Diagnostic programs

The display shows a list with program options for Diagnostics.



Select Rheobase and Chronaxie

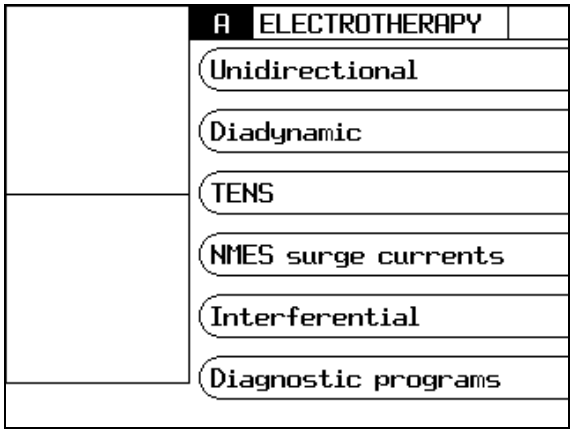
Subsequently the parameter window Rheobase is displayed.



See Chapter 8: DIAGNOSTIC PROGRAMS for detailed information about the diagnostic possibilities of the Combi 500 unit and paragraph 6.6 for more information on how to adjust the parameters.

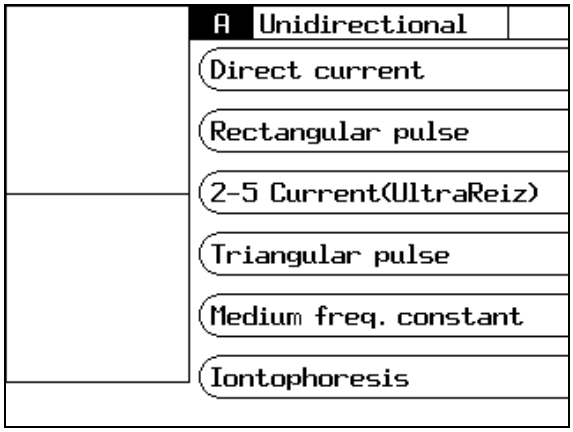
5.8 Direct selection of a CURRENT SHAPE

Push the key Electrotherapy
The display shows several main groups of the current shapes (see below).
In this manner one finds and selects the desired current shape very quickly.



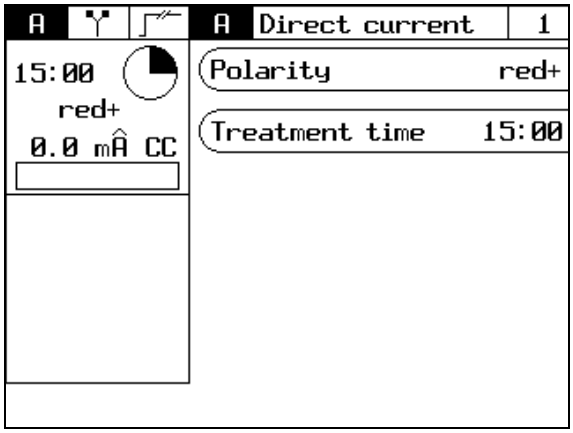
Select Unidirectional

The display shows a list of current shapes from which one can choose.



Select Direct current

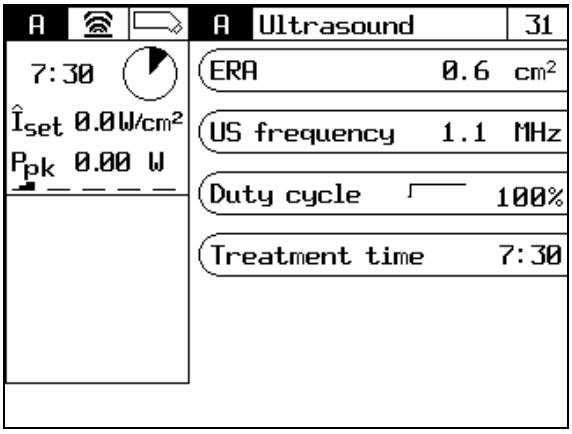
The display immediately shows the parameters of the selected current shape.



See Chapter 14: SPECIFICATIONS for an overview of the current shapes and their parameters and paragraph 6.6 for more information on how to adjust the parameters.

5.9 Direct selection of the ULTRASOUND THERAPY

Push the key Ultrasound therapy
The display immediately shows the treatment screen (see below).
The treatment is started immediately after turning open the intensity.



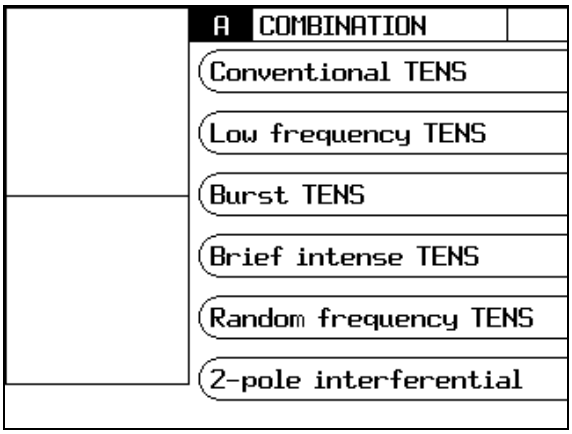
ATTENTION:
- Before starting a US treatment, one must first apply GymnaUniphy Contact-Gel to the treatment surface of the US head.
- Move the US head dynamically on the skin during the treatment, in order to prevent too high intensities on one single spot (which could cause burns!).

NOTE:
It is not possible to select 2 US treatments at the same time. When there is no US head connected, the parameter 'ERA' remains empty. In the channel window, no US head symbol is displayed. In the lower part of the screen, a message is displayed.

5.10 Direct selection of the COMBINED THERAPY

Push the key Combined therapy

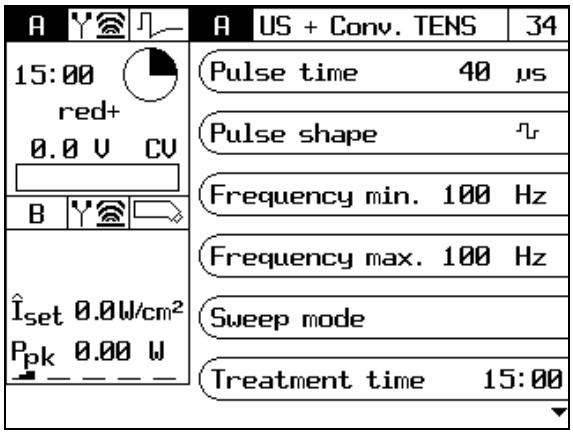
The display shows a list of 6 different current shapes for the Combined therapy. One has to make a choice out of this list (see below). One has to select the current shape by which one wants to apply the Combined therapy.



Select Conventional TENS

The control button for the intensity of channel A is <u>always</u> for the Electrotherapy part.

The control button for the intensity of channel B is <u>always</u> for the Ultrasound part.



See paragraph 6.12.7 for further explanation.

ATTENTION:

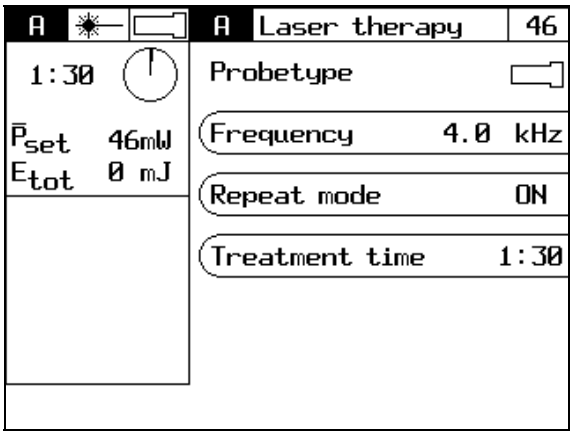
- The safety standards for the Combined therapy recommend a current density of 2.0 mA_{rms}/cm^2. Exceeding this limit might cause skin irritation and burns.
- Before starting a US treatment, one must first apply GymnaUniphy Contact-Gel to the treatment surface of the US head.
- Move the US head dynamically on the skin during the treatment, in order to prevent too high intensities on one single spot (which could cause burns!).

NOTE:
When a therapy is already administered through one channel, it is not possible to select the Combined therapy. The ongoing treatment has to be terminated first in such a case.

5.11 Direct selection of the LASER THERAPY

Press the key Laser therapy

The display immediately shows the treatment screen (see below). The treatment is started the moment one activates the pushbutton on the laser probe.



See paragraph 6.6 for more information about the modification of the parameters.

OPERATING SAFETY OF THE LASER THERAPY:
- *See paragraph 2.3.2.*

NOTE:
If there is no laser probe connected, then the parameter Probe type remains empty.
There is no representation of a symbol Probe in the channel window.

5.12 Selection of a treatment out of the MEMORY

One can store treatments in the memory and recall the stored treatments.

See Chapter 9: TREATMENT MEMORY for a detailed discussion about this principle.

6 GENERAL OPERATING INSTRUCTIONS

6.1 Introduction

The Combi 500 offers numerous possibilities and still remains very easy to operate. The operating principle is logical and consistent. As soon as one gets acquainted with the functions of the various keys and controls, the operational use of the unit is self-explanatory.

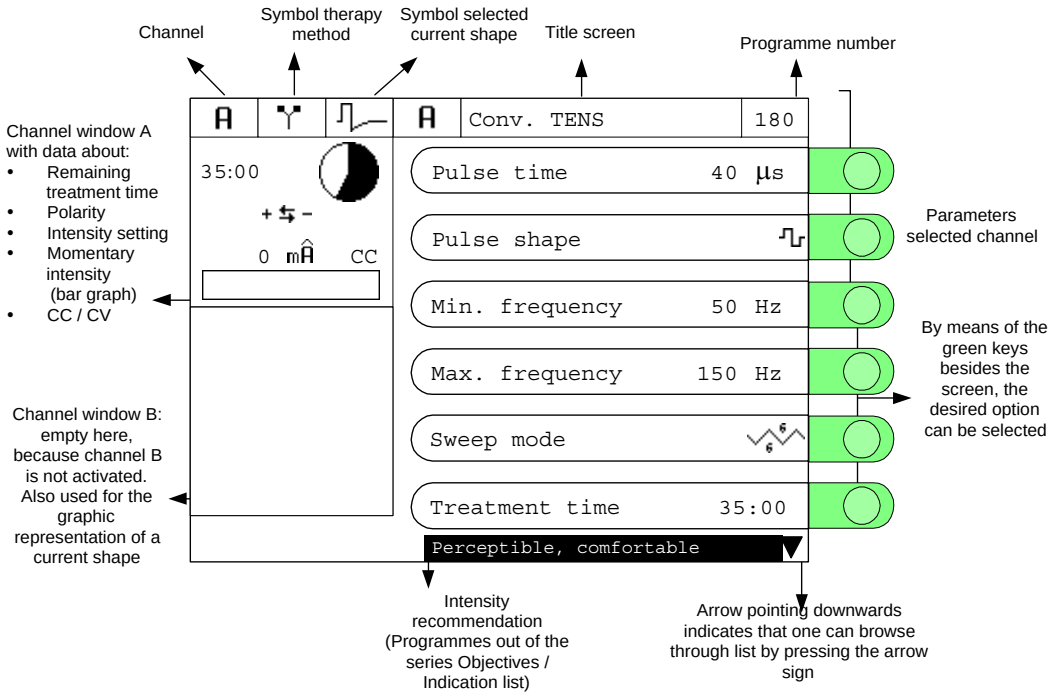
In this chapter, the functions of the keys and controls not yet treated previously will be discussed.

See Chapter 4: CONTROLS for a short and concise description of the controls, the numbers of these controls correspond to the numbers of the exploded view of the Combi 500 unit and its accessories in the beginning of these Operating Instructions.

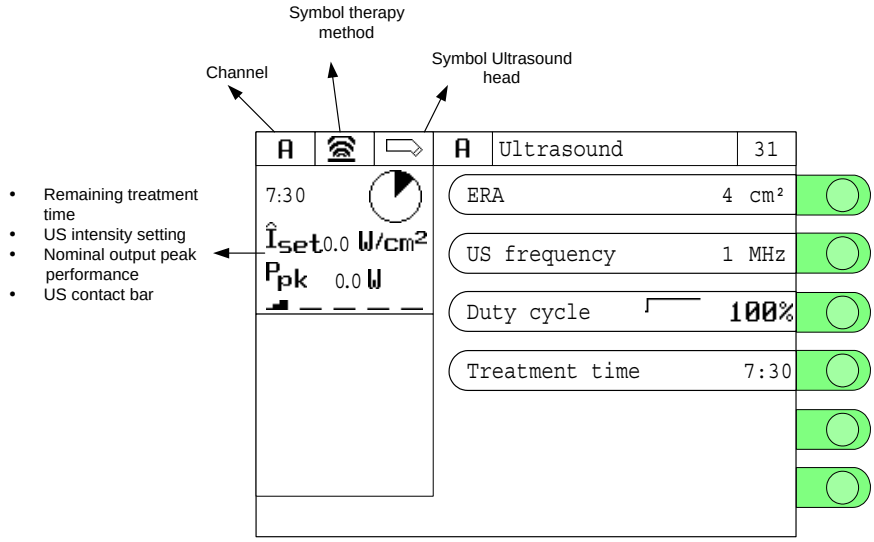
See Chapter 7: SOME PARTICULAR THERAPEUTICAL AND PARAMETER POSSIBILITIES.

See Chapter 18: INDEX for the alphabetical index. Here one can quickly find out on what pages of the Operating Instructions the specifically searched reference is discussed.

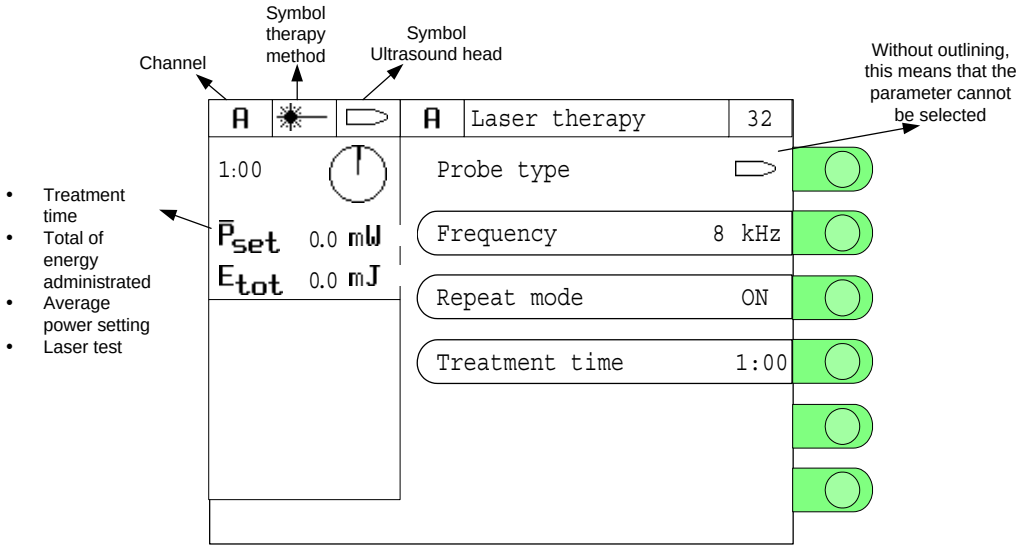
6.2 Electrotherapy – Display


Channel
Symbol therapy method
Symbol selected current shape
Title screen
Programme number
Channel window A with data about:
• Remaining treatment time
• Polarity
• Intensity setting
• Momentary intensity (bar graph)
• CC / CV
Conv. TENS
180
35:00
0 mA CC
Pulse time 40 µs
Pulse shape
Min. frequency 50 Hz
Max. frequency 150 Hz
Sweep mode
Treatment time 35:00
Perceptible, comfortable
Parameters selected channel
By means of the green keys besides the screen, the desired option can be selected
Channel window B: empty here, because channel B is not activated. Also used for the graphic representation of a current shape
Intensity recommendation (Programmes out of the series Objectives / Indication list)
Arrow pointing downwards indicates that one can browse through list by pressing the arrow sign

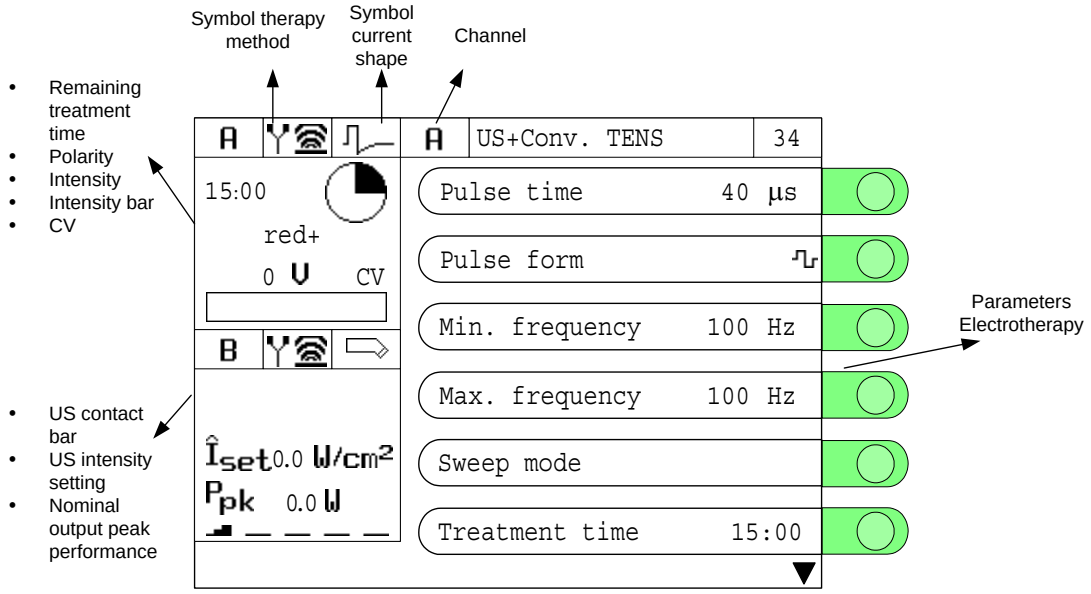
6.3 Ultrasound therapy – Display

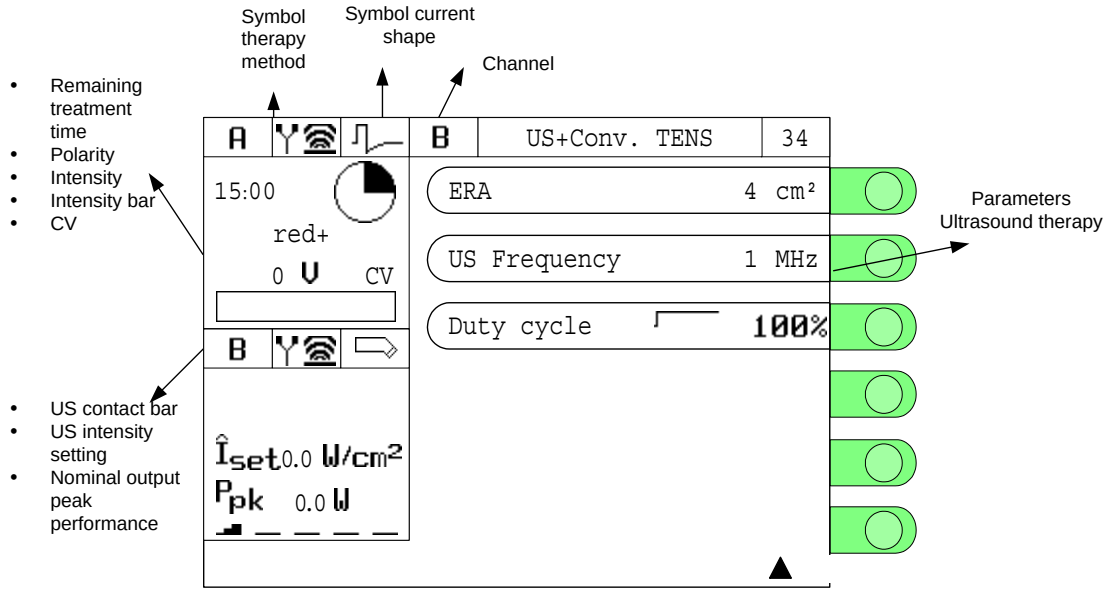


6.4 Laser therapy – Display



6.5 Combined therapy – Display





6.6 Green keys – select menu or select parameter / modify

The function of the green keys is different from program to program and from menu to menu. This function corresponds to the item next to the green key.

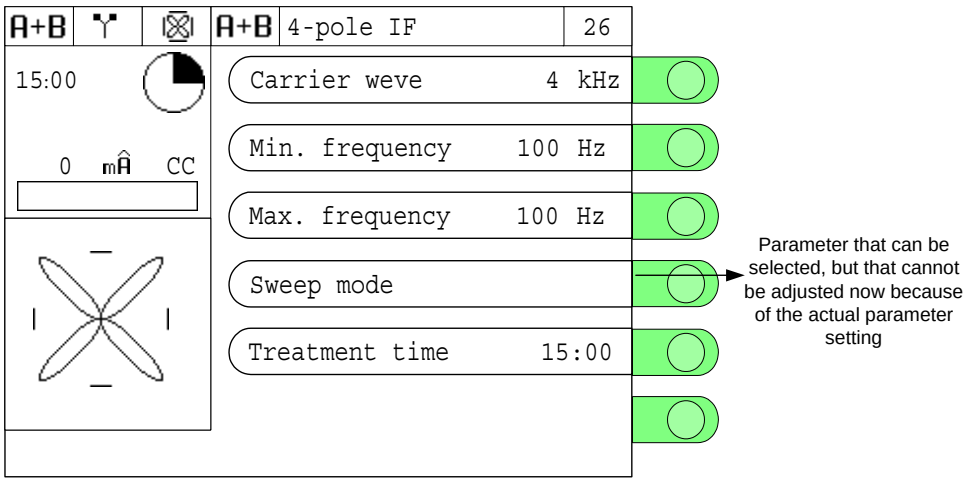
Through these keys:
a) one selects a menu;
After this selection one is automatically guided into the next display.
That way, one is guided step by step to a program display/treatment display.
b) one selects a parameter;
c) one modifies the selected parameter;
In order to modify the selected parameter one proceeds as follows:

- parameters subject to modifications are outlined.
- A selected parameter remains during 3 seconds into 'reverse or negative image'. As long as the parameter remains in this reverse image, one can modify the parameter by means of the keys and

NOTE:
At the lower side of the screen one can see the setting range of the selected parameter (in 'reverse/ negative image').

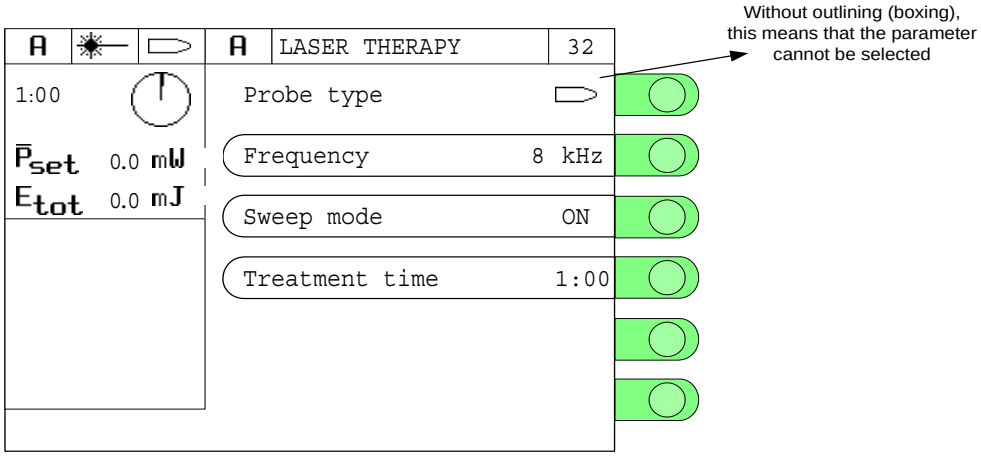
Specific parameters are outlined and cannot be modified anyhow. Such a parameter can be selected however for the function HELP ?

If in the event of Interference (see below), the minimum frequency is equal to the maximum frequency, the modulation time is not relevant, and it cannot be modified either.



Parameters that cannot be selected (and that cannot be modified) are not outlined (exception is the Electrode Placement).

In the case of a Laser therapy, the parameter «type probe» (see below) is not subject to be selected.



6.7 The UP- and DOWN-keys ▲ and ▼

These keys have a double function:

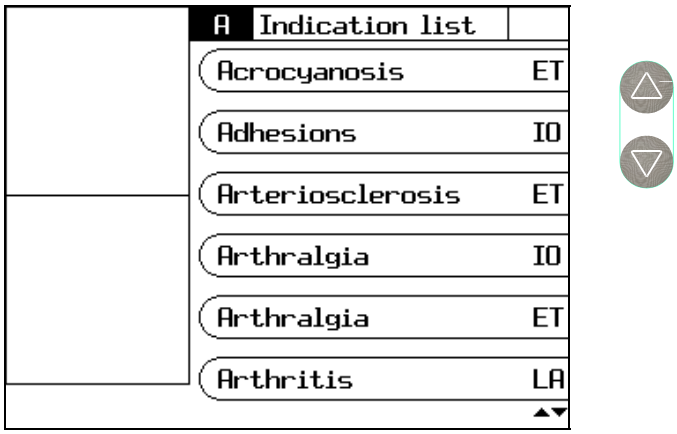
1) they allow browsing through a list,
2) they make it possible to modify the value of parameters.

6.7.1 Browsing with the keys ▲ and ▼

In the event that the screen shows more than 6 menus or parameters to make a selection, one can be transferred into different menus or parameters with the help of these keys. The browsing direction is indicated in the lower right corner of the display.

NOTE:
This is only possible when no menu or parameter has been selected.

Browsing can be done up or down. The browsing direction is visualised by the signs σ and τ in the lower right corner of the display (see below).



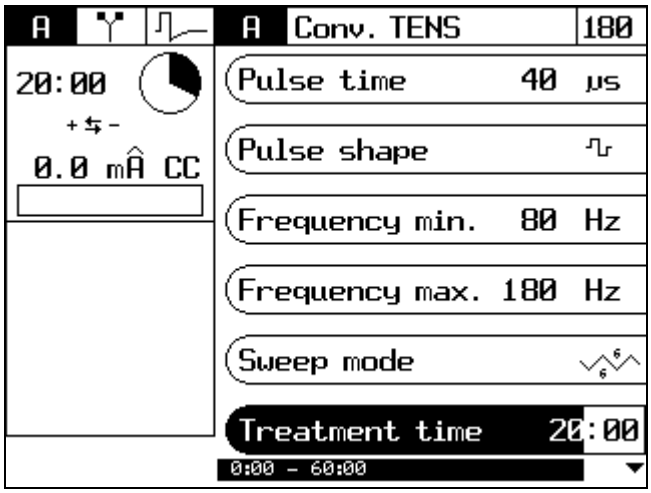
6.7.2 Modifying parameters with the help of the keys and

One can modify the value of a selected parameter with the help of these keys.
The longer one presses the key, the quicker the values modify.

NOTE
When releasing a key and subsequently pressing the key again, the values will modify very slowly again. When pushing the key even longer, the modifications will be carried out at a higher speed again.

The lower line of the display gives the setting range of the selected parameter.

The parameter TREATMENT TIME (see below) can be modified using the keys and
- press 1 x the Green Key: time modifies by the minute.
- press 2 x the Green: time modifies by the second.



6.8 Return key

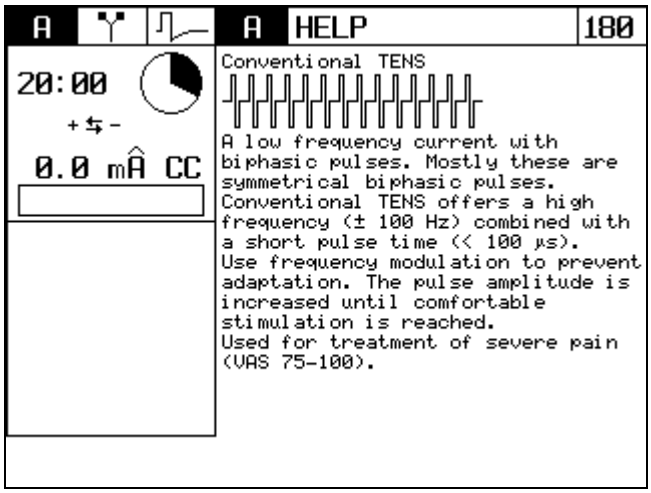
This key allows you to return to the previous window.

EXCEPTION : one can browse through a list (e.g. an Indication list) by using the keys and .
If one is inside a list, one can always go back to the previous menu by pressing the Return key

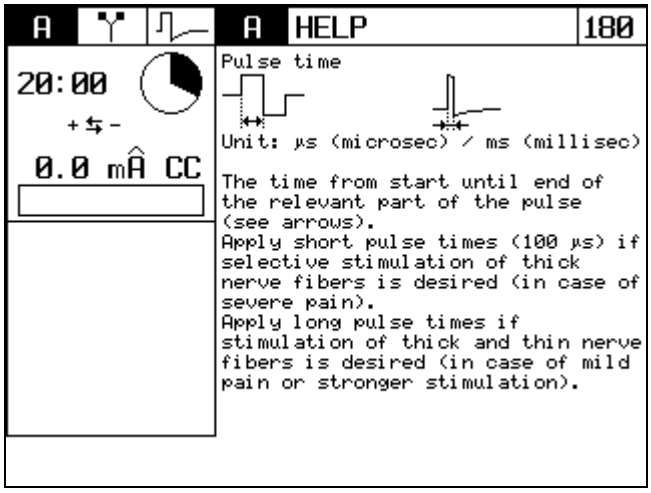
6.9 Help key ? - Request detailed explanation

The Combi 500 assists to the maximum extent possible when setting up therapeutic treatment.
Depending on the menu one is working in, it is possible to request some background information with the aid of the Help key ?

If no parameter is selected (see below), one receives background information concerning the current shape by pressing the Help key ?


A
A HELP
180
20:00
+ ⇆ -
0.0 mÂ CC
Conventional TENS
A low frequency current with biphasic pulses. Mostly these are symmetrical biphasic pulses.
Conventional TENS offers a high frequency (± 100 Hz) combined with a short pulse time (< 100 µs).
Use frequency modulation to prevent adaptation. The pulse amplitude is increased until comfortable stimulation is reached.
Used for treatment of severe pain (VAS 75-100).

In the event that a parameter has been selected (see below), one receives background information concerning the parameter by pressing the Help key ?


A
A HELP
180
20:00
+ ⇆ -
0.0 mÂ CC
Pulse time
Unit: µs (microsec) / ms (millisec)
The time from start until end of the relevant part of the pulse (see arrows).
Apply short pulse times (100 µs) if selective stimulation of thick nerve fibers is desired (in case of severe pain).
Apply long pulse times if stimulation of thick and thin nerve fibers is desired (in case of mild pain or stronger stimulation).

NOTE:
If the parameter cannot be selected (and is thus not outlined), information about this parameter is offered through the parameters that can be selected (they are outlined) and that are in direct relation to the envisaged parameter.

By means of the Return key ⮌ one goes back to the previous display starting from the Help window.

6.10 Channel selection key A or B

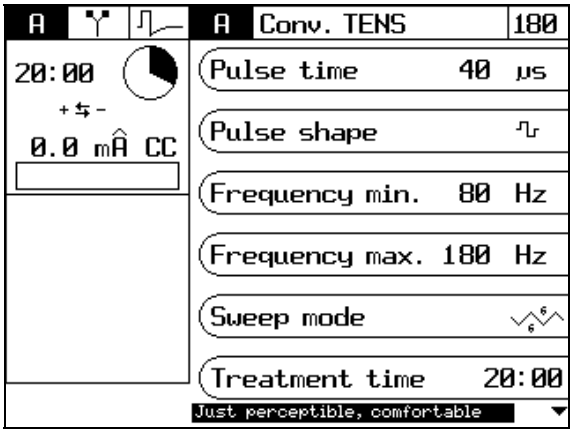
The Combi 500 has two different channels independent from each other (A + B), that can be selected using the Channel selection key

When starting up, the Combi 500 unit automatically selects the channel A.

Both channels are selected automatically:
- in the case of Tetrapolar current shapes,
- in the case of the selection of the option «Alternating channels»
- in the case of the Combined therapy (channel A = Electrotherapy, channel B = Ultrasound therapy).

ATTENTION:
- It is only possible to adjust the parameters of the **selected channel**.

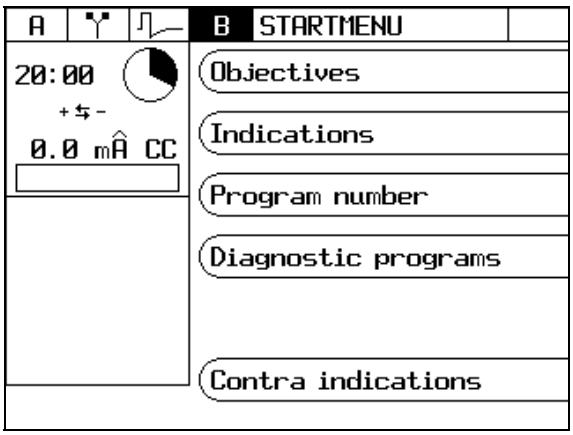
When starting up, the Combi 500 unit automatically selects the channel A (see below).



Press the Channel selection key

Channel A is active already.

It is now possible to set up a treatment at channel B.



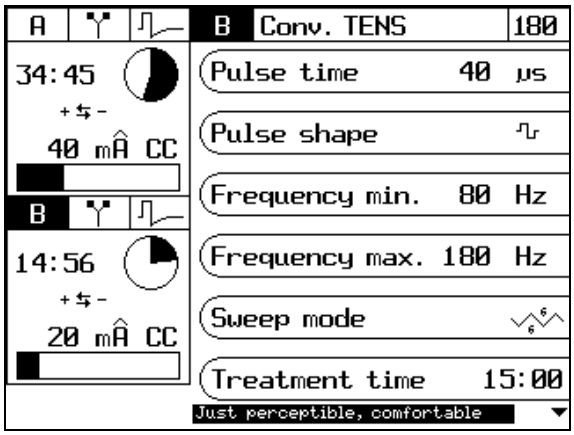
6.11 Enter key - call intensity display

As soon as parameters are adjusted for one of the channels (A or B), one can call up the intensity display by means of the Enter key

This screen gives the most important information - conveniently arranged and well readable – and provides a steady image to the patient.

NOTE:
Only those channels of which the parameters are adjusted, are visible on the intensity display.

In the example below (see below) channel A as well as channel B are adjusted.
The intensity display can be called by means of the Enter key

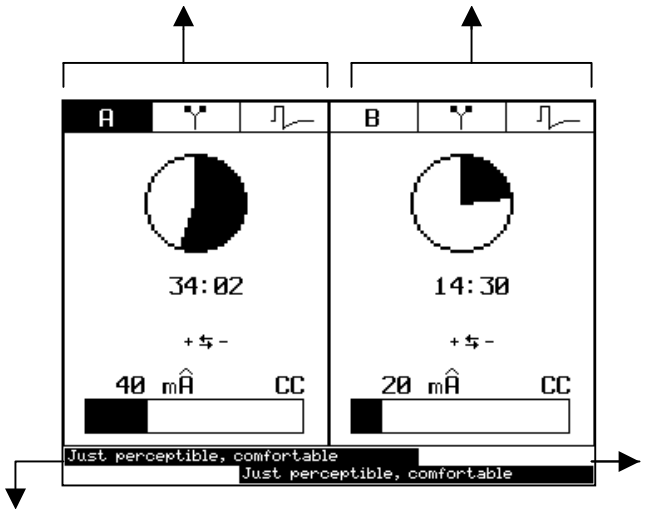


Press the Enter key

The example of the amplitude display (see below) is valid for Electro therapy, (with the exception of sequential and diagnostic programs), Ultrasound therapy, Combined therapy and Laser therapy.

Amplitude screen channel A or with 4-pole interferential for A+B

Amplitude screen channel B. Sometimes used for graphic representation of the current



Message line for channel B

Message line for channel A

If a message appears both for channel A and B, it will be aligned in the middle

6.12 Intensity buttons A and B - content of the channel windows

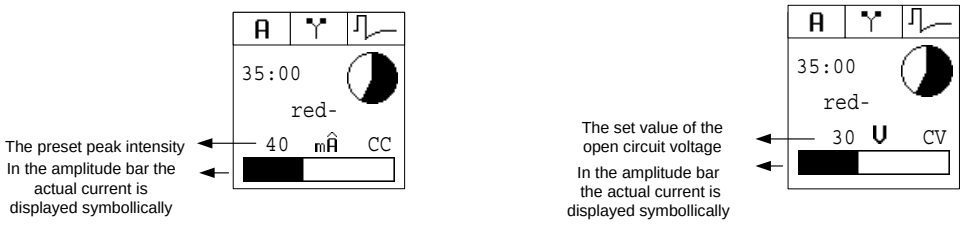
With the intensity buttons- channel A by means of button A and the channel B by means of button B one can adjust the intensity of the envisaged channels.

The left hand side of the display shows as to what the envisaged channel windows is concerned:

- the set intensity
  - at Constant Current* in milliampères (below at the left hand side)
  - at Constant Voltage* in Volts (below at the right hand side)
- the treatment time.

In both cases the intensity bar represents the adjusted and set current in a symbolic way.

** Also refer to paragraph 7.7*


35:00
red-
40 mA CC
The preset peak intensity
In the amplitude bar the actual current is displayed symbollically
35:00
red-
30 V CV
The set value of the open circuit voltage
In the amplitude bar the actual current is displayed symbollically

6.12.1 Electrotherapy 4-poles – adjust intensity

In the case of 4-pole current shapes, both the channels A and B are active simultaneously. Presetting the intensity is in this case always carried out by means of the LEFT intensity button A
The display then shows the preset intensity in the envisaged channel window.

6.12.2 Bursts – adjust intensity

In the case of burst currents there is a certain serial interval (stimulus time) and a serial pause (stimulus pause). As soon as one turns at the intensity button in the case of bursts a new serial interval is started automatically. That is the reason why one does not have to take into account the serial interval and pause, when opening up the dose.

6.12.3

Alternating channels - adjust intensity

Refer to paragraph 7.12 for more information about the alternating channels.

They are bursts too and thus one can speak of a certain serial time and pause.
The conduct is the same as the one described in *paragraph 6.12.2*.

NOTE:
Due to the fact that the channels are operating alternatively, there is never a question of simultaneous stimulation on both channels.

How does the Combi 500 unit react if the intensity control button of the channel is turned, that is in a serial pause at that very moment (the stimulation is than present on the other channel) ?

The active channel is switched back to zero as expeditiously as possible. After that, the channel that the therapist wants to become active is adjusted with a new intensity, which is immediately sensed by the patient. In the event that no new dose is set, the Combi 500 unit proceeds the treatment according to the preset parameters.

6.12.4 Iontophoresis – adjust intensity

In a certain number of programs for Diagnostics and in the case of programs for Iontophoresis, the intensity is modified:

- in steps of 0.1 mÂ, from 0 to 20 mÂ;
- in steps of 1 mÂ, above 20 mÂ.

- For safety reasons we strongly recommend a maximum intensity per electrode-surface:
- Intermediate frequent rectified rectangular current: 0.25 mÂ x electrode-surface area in cm^2.
- Rectified direct current: 0.20 mÂ x electrode-surface area in cm^2.
- If the maximum recommended intensity is exceeded, the message 'Risk for skin deterioration' will be displayed.

IMPORTANT:
Before boosting the intensity, one has to fill in **oneself** the electrode surface area. This is **not done automatically**!
For Iontophoresis a sterilised gauze has to be used. For more information you can select the parameter INFORMATION in the Iontophoresis program.

WORK IN A SAFE WAY:
When applying Iontophoresis, the intensity is adjusted between 0 - 20 mÂ in steps of 0.1 mÂ. In that manner a very accurate dosing is possible.
In order to prevent cauterisation or burns we recommend the use of a maximum intensity of 0.1 mÂ/cm^2.

6.12.5 Sequential programs – adjust intensity

This is a sequence with a pre-programed succession of current shapes following each other in a “step by step” mode, after a preset time frame. The desired intensity is adjusted during the first sequential step.

NOTE:
In order to protect the patient, switching to the next sequential step is not always possible at the same intensity level. Every now and then it is necessary to adjust the intensity manually or to restart at the very beginning.

See paragraph 7.6 for more elaborate information about Sequential programs.

6.12.6 Ultrasound therapy - adjust intensity

- The **Îset** indicates the preset ultrasound intensity.

- The **Ppk** indicates the real peak ultrasound output power.

When adjusting the intensity by means of the intensity control buttons A and B the Iset-value will change on screen.

If there is sufficient contact with the skin, the peak output power is displayed.
If there is an insufficient contact with the skin, the peak output power is 0.0 W.

ATTENTION:
- Before starting the US treatment, one has to apply GymnaUniphy Contact-Gel upon the area to be treated.
- The US head must be moved dynamically during the treatment in order to prevent a high intensity at one spot (burns!).

6.12.6.1 Contact-control – graphical representation

The Combi 500 unit gives a feedback of the contact-control of the US head to the patient’s skin. Here below, you see an overview of the graphical representation.

1. Contact detection bar I = zero	
2. Contact detection bar: bad contact	
3. Contact detection bar : sufficient contact	
4. Contact detection bar: good contact	
5. Contact detection bar: very good contact	

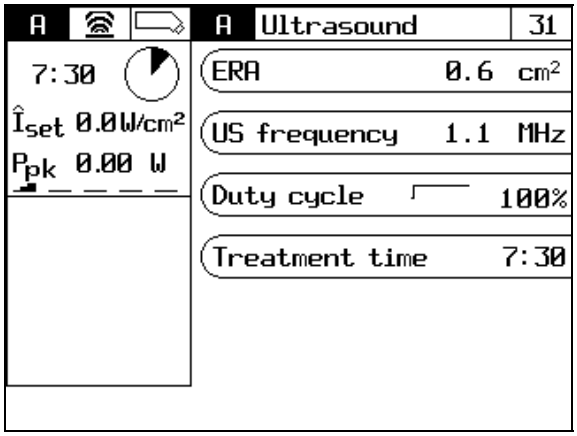
NOTE**:**
In the event of a bad contact (2), the treatment time and the Ppk will go to 0.0 Watt. Whenever there is sufficient contact again (3), the treatment time resumes its course and the peak output power is displayed once again.

6.12.6.2 Multi-frequent Ultrasound head in the case of a US therapy

One can connect two US heads to the Combi 500 unit. The Combi 500 always selects the head that was connected in the last position. The other US head connected is selected by modifying the parameter ERA.

The parameter ERA can only be adjusted if there are two US heads connected (see below). ERA can be modified by means of this parameter, that is to say that one changes the US head.

In order to test the US head before starting a treatment, one can immerse the US head in a bowl of water (18 °C). Increase the intensity and check in the channel window if the Ppk increases.



With this parameter, one can modify the ERA. This means a swapping of the US heads

There are two indicator lights on the US head. They give information about the US emission.

Blinking green light	The US head is properly connected.
Continuous green light	The US head is selected.
Continuous yellow light	There is US -emission.
Blinking yellow/green light	There is no contact with the skin.
Blinking yellow light	End of the treatment.

6.12.7 Combined therapy - adjust intensity

During the Combined therapy both channels A and B are active simultaneously. The setting of the Intensity for the Electrotherapy is in this case always done by means of button A

The setting of the Intensity of the Ultrasound than always happens with button B

On screen one can read the adjusted values on the relevant channel windows.

ATTENTION:
- The safety standards of the Combined therapy recommend a current density of 2.0 mA_{rms}/cm^2. Exceeding this limit can cause skin irritation and burns.
- Before starting the US treatment, one has to apply GymnaUniphy Contact-Gel upon the area to be treated.
- The US head must be moved dynamically during the treatment in order to prevent a high intensity at one spot (burns!).

6.12.7.1 Multi-frequent Ultrasound head used during the combined therapy

Refer to paragraph: 6.12.6.2. for the behaviour of the multi-frequent US head during the ultrasound therapy.

Whenever there is a bad contact between the US head and the skin,

- The adjusted intensity (in Volts) for the Electrotherapy remains unchanged,
- The intensity (visible on the intensity bar) remains unchanged,
- The treatment time stops,
- The Ultrasound peak power Ppk goes to 0.0 Watt.

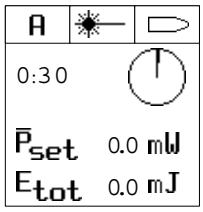
As soon as there is again sufficient contact, the intensity for the electrotherapy as well as for the Ultrasound (peak power) increases. The treatment time also resumes its course.

NOTE:
The contact detection bar represents the contact situation graphically *(see paragraph 6.12.6.2).*

ATTENTION:

- The safety standards of the Combined therapy recommend a current density of 2.0 mA_{rms}/cm^2. Exceeding this limit can cause skin irritation and burns. Before starting the US treatment, one has to apply GymnaUniphy Contact-Gel upon the area to be treated.
- The US head must be moved dynamically during the treatment in order to prevent a high intensity at one spot (burns!).

6.12.8 Laser therapy - total energy dissipated



During the laser therapy no use is made of an intensity regulator. The treatment time and the frequency are filled in; the treatment is started by pressing the push button on the laser probe. The push button must be pressed and held during the complete treatment. Only under these conditions is there laser emission and the treatment time is running as well.
As the treatment time passes by, the **Etot**-value increases in nominal value every second with a value called **P_{set}**.

$\bar{P}_{set}$: this is the preset average laser power.
It is the product of the energy per impulse and the frequency and it is expressed in microWatt (µW) or milliWatt (mW).

E_{tot}: it is the total of administered laser energy of the current treatment.
It is the product of Pset and the treatment time and it is expressed in milliJoules (mJ) or Joules (J).

6.12.8.1 Laser probe

One laser probe can be connected to the Combi 500 unit. The Combi 500 always displays the connected Laser probe on the screen if the Laser therapy has been selected. There are two indicator lights on the Laser probe representing the activity of the probe.

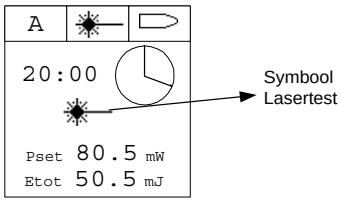
The following activities are possible:

Continuous yellow light	The laser probe is active and there is emission.
Continuous green light	The laser probe is detected but there is no emission.

6.12.8.2 Testing the Laser probe –during the treatment

One can test if the Laser probe actually emits with the Laser eye [19] .
The Laser probe is tested as follows:

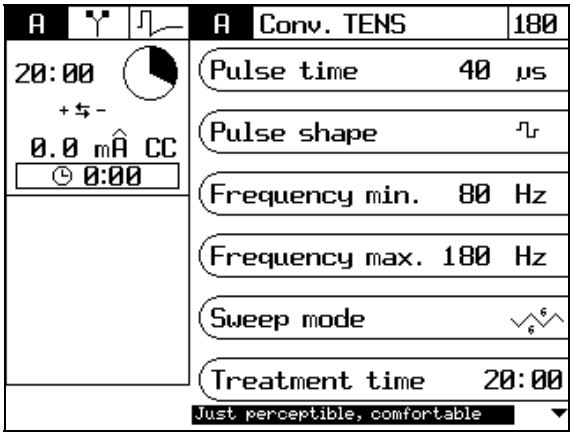
Go to the parameter- or intensity screen for the Laser therapy.
- Put the Laser probe in its upright position just straight on the Laser testeye[19].
- Press the key on the Laser probe.
- The symbol Laser test appears in the intensity window.



If one wants to test the Laser probe in a more specific way, this should be done by means of System settings, *see paragraph 10.9.*

6.12.9 Intensity - end of treatment, content of the channel windows

If the treatment time is set, its countdown starts until the intensity is tuned open. In the case of Laser therapy the treatment time is counted down until the push button is pressed on the probe itself. As soon as the treatment time is over, the units gives a beep signal; the intensity is automatically running back to zero. In the intensity bar, a symbol indicates that the treatment is over (see below) For the Ultrasound this symbol is coinciding with the **Ppk** value.



NOTE:
In the case of a Laser therapy this symbol 'end of treatment' will not appear. The **Etot-value remains** on screen (total of the administered laser energy of the current treatment), and this until a new laser treatment can be started.

If the treatment time is set to 0:00, (only possible for Electrotherapy programs), one determines oneself the moment when the treatment should be finished and this by turning the intensity back (to zero).

6.13 Pause key - interrupt the treatment temporarily

If - during a current treatment – one presses the Pause key , in the at that very moment selected channel (in the case of 4-pole current shapes both channels) the treatment time will stop, while the intensity runs back to zero.

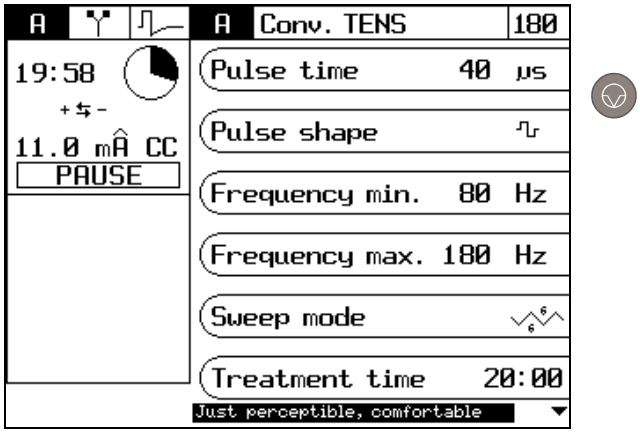
There are no changes to the parameter setting of that specific channel.

When one presses the Pause key **a second time** start, the treatment is started up again. The intensity gradually increases up to the preset level before and the treatment time starts running again.

In order to put the other channel that is active at that very moment, into the pause position, this channel must be selected first before pressing the Pause key

For the Electrotherapy (see below) the intensity bar indicates that the channel is in the Pause state.

In the case of Ultrasound the Pause comes instead of the **Ppk** value.

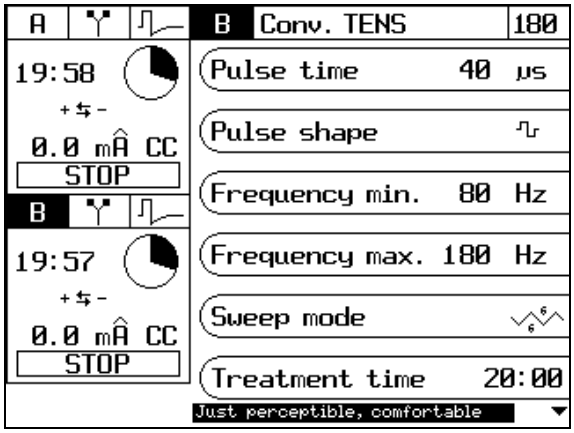


NOTE:
The Laser therapy cannot be set in pause. In the case of Laser therapy it is sufficient to release the probe, the laser is than in a sort of pause state. The **Etot-**value remains indicated in the relevant channel window.

6.14 Stop key - interrupt the treatment immediately

As soon as the patient or the therapist presses the Stop key during the treatment, the intensity is immediately reset to zero for all active channels. In the event that one would have changed the parameter settings of the current shapes for instance, the modified parameter setting would remain on screen. In order to proceed with the treatment, one must adjust the intensity once again.

During the Electrotherapy (see below) the intensity bar indicates that the channel is in the Stop position.
In the case of Ultrasound, the stop comes instead of de **Ppk** value.



NOTE:
The Laser therapy cannot be set in the stop mode. In the case of Laser therapy it is sufficient to release the probe, the laser is than in a sort of pause or stop state. The **Etot-**value remains indicated in the relevant channel window.

6.15 Starting up the unit out of STAND-BY

If the Combi 500 unit is not used during 10 minutes, the appliance automatically switches to the 'Stand-by' [35] mode.

The screen and the background lighting distinguish and the yellow indicator light ⏻ remains illuminated. A simple push on any key makes the unit ready for use again.

See Chapter 10: SYSTEM SETTINGS AND BASIC SETTINGS to modify the Stand-by time.

7 SOME PARTICULAR THERAPEUTICAL AND PARAMETER POSSIBILITIES

7.1 Introduction

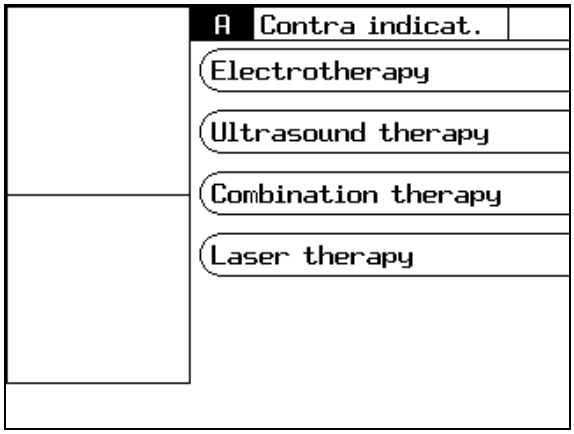
In Chapter 6 The general Operating Instructions of the Combi 500 unit have been treated.

The Combi 500 unit offers a certain number of particular current shapes and/or parameters.
When having questions about certain current shapes or parameters, we recommend the use of the HELP key ? . The questions are answered in an expeditious and simple manner.

7.2 CONTRA-INDICATIONS on the display

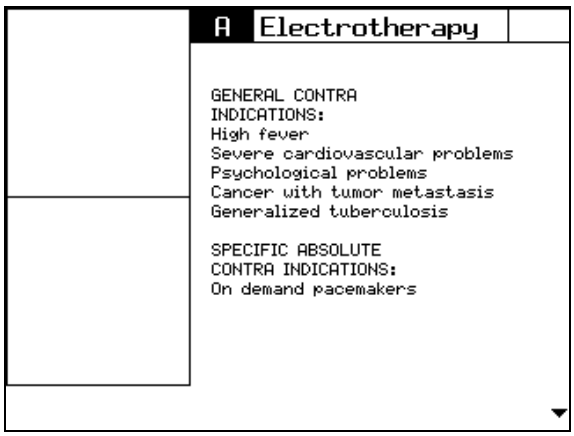
The Start menu offers the option Contra-indications at the lowest line of the display.

During the selection of the Contra-indications the screen gives a certain number of therapeutical possibilities (see below), from which one has to be selected.



Select Electrotherapy

Subsequently, a list with Contra-indications follows with reference to the Electrotherapy.



One can browse through the list with the keys and

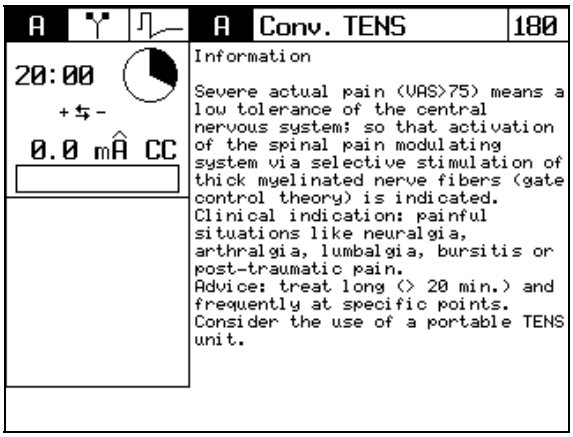
With the use of the Return key one returns back to the Start menu.

See Chapter 11: INDICATIONS AND CONTRA-INDICATIONS for more information.

7.3 The option INFORMATION

When selecting a treatment by means of the input Objectives or Indications list, one encounters the option Information on the parameter screen.

When selecting Information, the display indicates the following information:
- motivation of the selection of the recommended treatment methodology and the parameter setting;
- advise about the frequency of the treatment;
- possible alternative treatments.

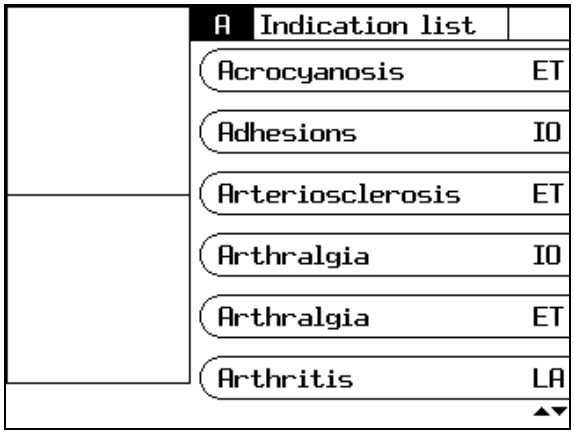

A
A
Conv. TENS
180
20:00
+ ⇆ -
0.0 mA CC
Information
Severe actual pain (VAS>75) means a low tolerance of the central nervous system; so that activation of the spinal pain modulating system via selective stimulation of thick myelinated nerve fibers (gate control theory) is indicated.
Clinical indication: painful situations like neuralgia, arthralgia, lumbalgia, bursitis or post-traumatic pain.
Advice: treat long (> 20 min.) and frequently at specific points.
Consider the use of a portable TENS unit.

When pressing the key Return one comes back into the previous screen.

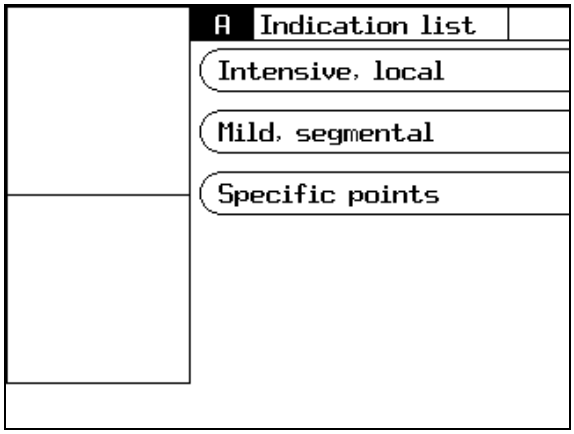
7.4 Electrode placement, ultrasound heads and laser probes

When selecting a program via the Indication list, one gets - if so desired - a recommendation about the exact emplacement of the Electrodes, Ultrasound heads Laser probes, with a reference to a clear and detailed colour picture in the TREATMENT GUIDE [47].

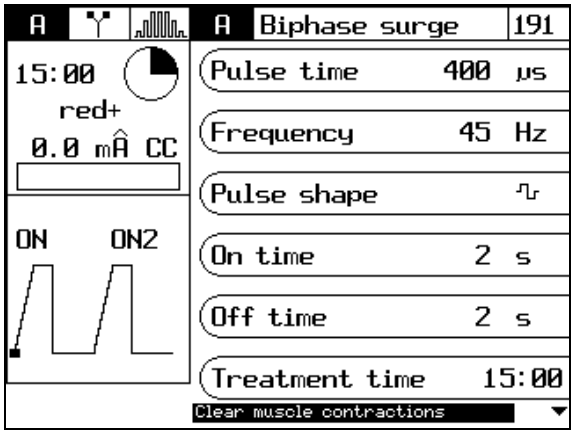
The next 6 displays show how one can find for instance via Electrode Placement the corresponding picture numbers in the Treatment Guide.



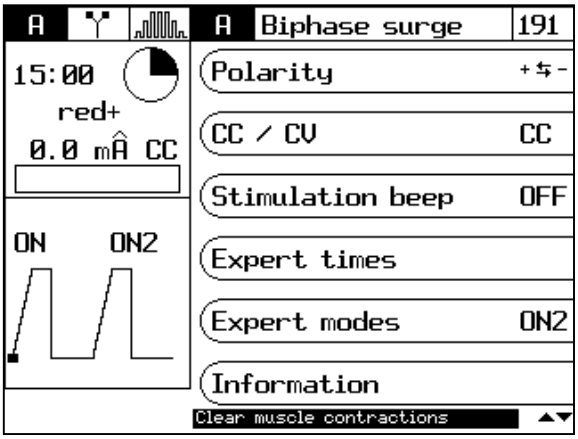
Select Arteriosclerosis



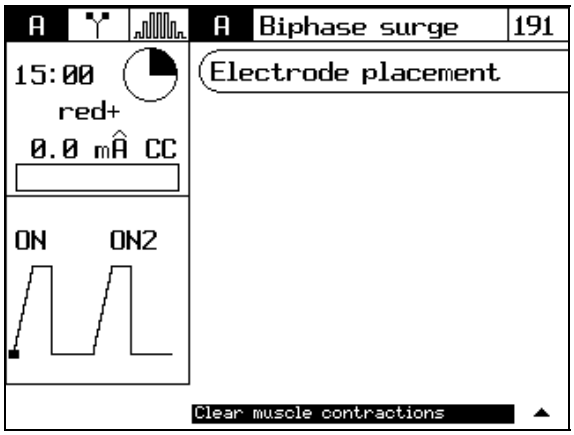
Select Intensive, local



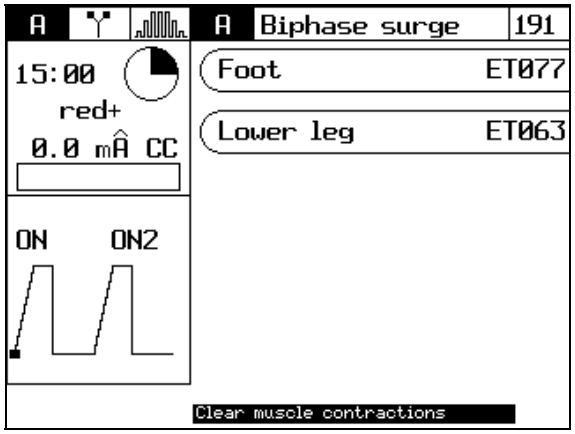
Use the key *to reach the next part of the parameter screen*



Use the key ▽ to reach the next part of the parameter screen



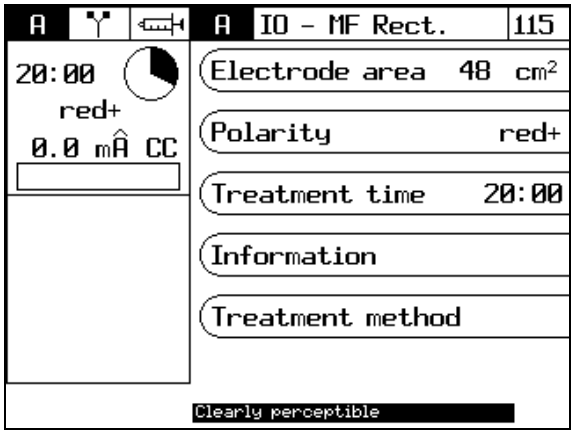
Select Electrode placement



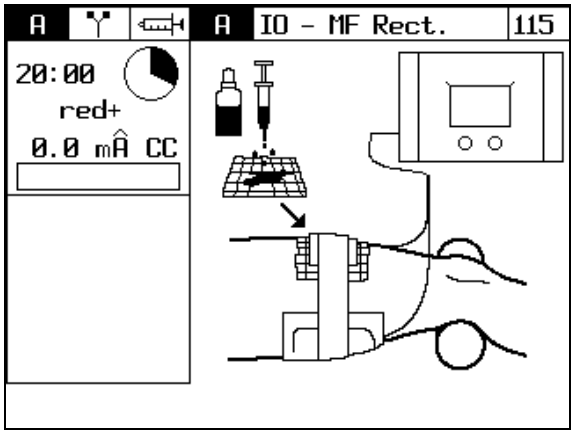
The number (ET077 or ET063) refers to the picture in the Treatment Guide

With the Return key ⮌ one comes back in the parameter screen.

In the case of Iontophoresis (see the next two screens below) the Electrode Placement is replaced by the Treatment method.



Select Treatment method



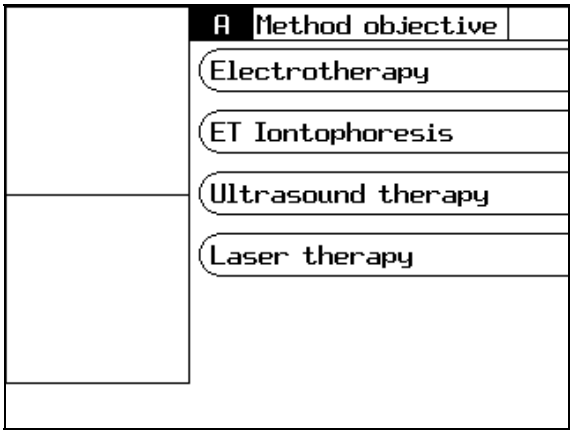
With the Return key one comes back in the parameter screen.

7.5 Iontophoresis

In the case of Iontophoresis medication is brought in the body as electrically charged particles (ions), by means of a direct current:

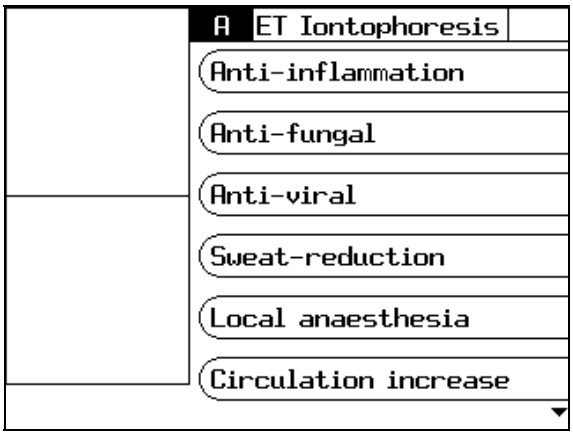
- Either by rectified continuous current;
- Or by intermediate frequent rectified rectangular current (most pleasant application as to what the patient is concerned).

Select the Start menu from the input Objectives, subsequently select the Therapy method (*see below, see also paragraph 5.4).*



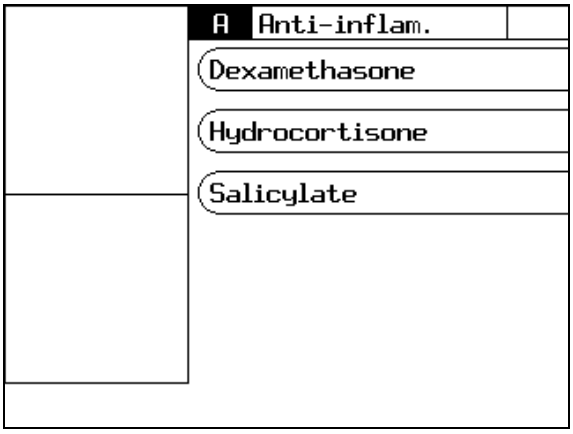
Select Iontophoresis

A list with objectives for Iontophoresis follows (see below).



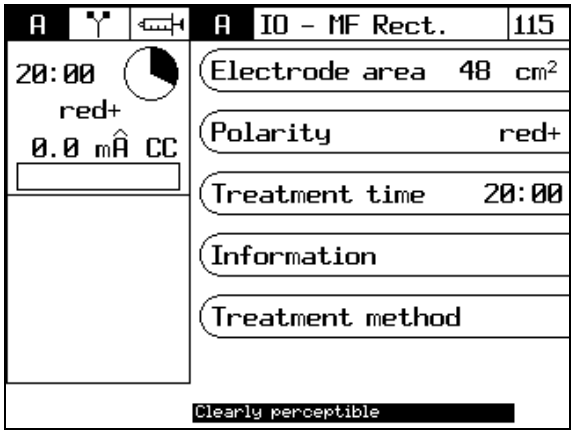
See Anti-inflammation

In a certain number of cases one can now make a selection for oneself out of a number of appropriate medications in accordance with the selected objective (see below).



Select Hydrocortisone

During the applications for Iontophoresis a recommendation for the intensity appears in the lower part of the display (see below).



- For safety reasons we recommend a maximum intensity per electrode-surface area.
- Intermediate frequent rectified rectangular shape current: 0.25 mÂ x electrode surface area in cm^2.
- Rectified continuous current: 0.20 mÂ x electrode surface area in cm^2.
- If one exceeds the maximum recommended intensity, the message 'risk for skin deterioration' appears.

IMPORTANT:
Before opening the intensity, one must fill in the electrode surface area used. This is not done **automatically**!
For Iontophoresis one must use a sterilised gauze. For more information: select the parameter INFORMATION of a program for Iontophoresis.

WORK SAFELY:
In the case of Iontophoresis the intensity is set between 0 - 20 mÂ in steps of 0.1 mÂ. This allows very accurate dosage.
In order to prevent cauterising or burns we recommend using a maximum intensity of 0.1 mA_{rms}/cm^2.

NOTE:
When selecting Iontophoresis via the input Rectified Currents (in the menu Electrotherapy) one selects the medication oneself out of the recommended list.

7.6 Sequential current shapes

7.6.1 Sequential current shapes – advantages

When selecting a therapy via the input Objectives, in most of the cases one gets the choice of a conventional simple therapy shape of a sequential therapy method.

A SEQUENCE is a pre-programd succession of current shapes following up each other in a "step by step" way, after a previously set time.

Advantages:
- in an Electrotherapy treatment some logically ordered objectives can be realised;
- if the objectives are identical, one can lay different accents;
- a build up is given that joins <preparation- most important effect – cooling>.

7.6.2 Sequential current shapes – intensity

Every sequential step is characterized by its own parameter settings and its own treatment time. Recommendations are given concerning the intensity to be applied.

What does the intensity do when switching to the next sequential step?
- If safety conditions permit doing so, the intensity, set in the previous step, is maintained.
- Or one has to apply a new intensity turning up the appropriate button from zero on.

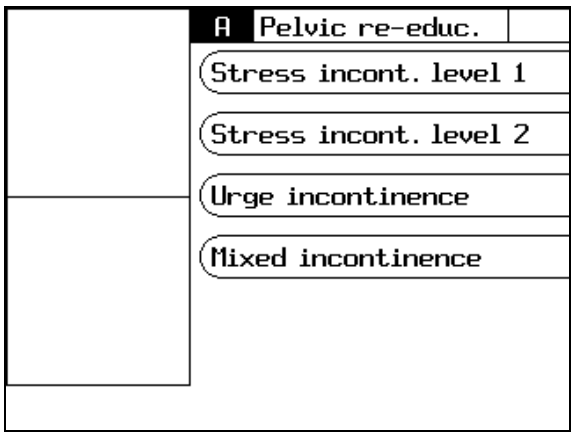
If there is an automatic intensity transfer for all sequences, the message 'AUTO' is displayed on screen just behind the sequential program number.

In the other case 'MANUAL' is displayed, meaning that the therapist himself must adjust once or several times to the recommended intensity during the treatment.

7.6.3 Sequential current shapes – selection

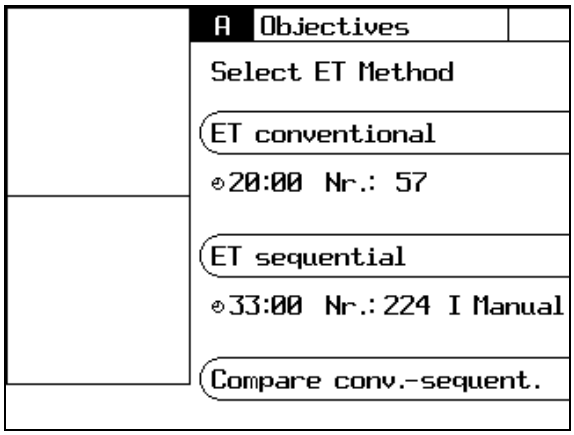
A sequential current shape can be adjusted:
- by using the input Objectives;
- or directly via the Program number.

In this example (see below) a sequential current shape is set via Objectives > Electrotherapy > Muscle training > Pelvic re- education *(see paragraph 5.4.for the setting of the Objectives).*



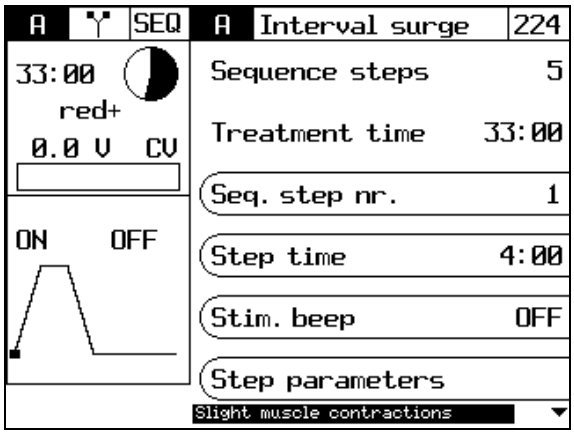
Select Mixed incontinence

Subsequently follows the choice between Conventional and Sequential (see below), and the mentioning of the treatment duration and the program number. (Sequential programs display whether or not the intensities are adjusted automatically or not when switching steps; <auto> or <manual>).

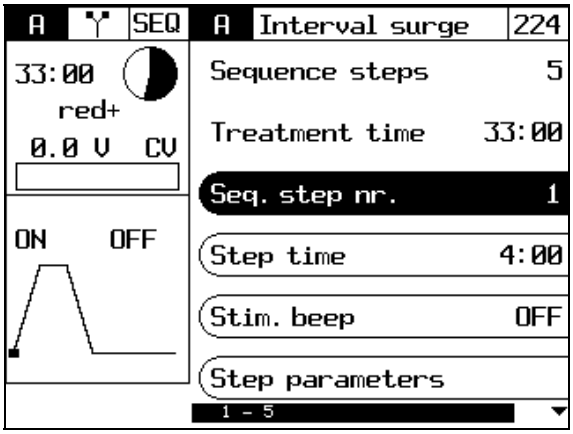


Select ET Sequential

The overview of the selected sequence appears on screen (see below). The treatment starts as soon as the intensity is turned on.



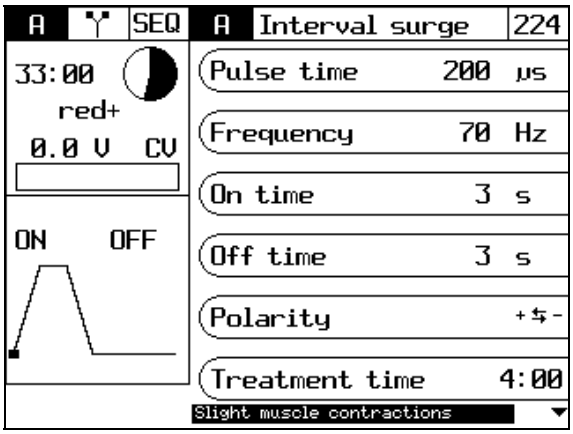
OR in this specific case the option Sequential step (see below) can be selected to choose the next sequence (e.g. when one wants to skip the preparatory part of the treatment).



Select Sequence step number

One can set a bigger step number by means of the key.
The option Step parameters gives detailed information about the parameters of the selected step.

The example (see below) shows the parameters of Sequence step 1.
Parameters of sequential current shapes cannot be modified. The treatment can also start beginning from this window and turning open the intensity.



With the aid of the Return key one is transferred back again into the overviewing display of the Sequences.

7.7 Constant Current - Constant Voltage

7.7.1 Generalities

The Combi 500 unit offers for a certain number of current shapes Constant Current as well as Constant Voltage. When applying a dynamic electrode technique, we recommend the use of the setting Constant Voltage. This prevents unpleasant sensations for the patient when moving back and forth with the electrode.

7.7.2 Pelvic re-education

The Combi 500 unit can be equipped with some probes for the treatment of incontinence complaints.

As soon as the vaginal or the anal probe is connected to the Combi 500 unit, the device will recognize this probe. In order to prevent unpleasant sensations the unit will only apply alternating currents with a Constant Voltage setting (TENS, NMES and 2-pole interferential currents) from now (this is done automatically). All other current shapes are inaccessible at that moment.

ATTENTION: The unit does **not** recognize the **rectal** probe. The device basically allows all kind of current shapes. However, we strongly advise the **sole use of a Constant Voltage setting when working with the rectal probe**.

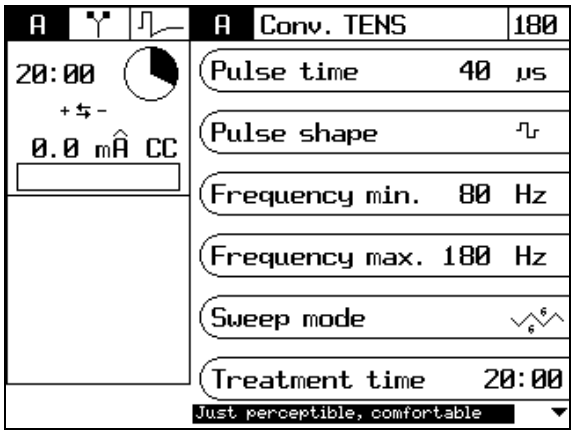
NOTE:
The application CC or CV is clearly indicated in the channel window.

7.8 Setting different current or therapy forms per channel (A + B)

The Combi 500 unit is equipped with two channels adjustable independently from each other. Thus, two indications, even with two different therapies, can be treated simultaneously. The manner if setting is very simple.

First, one has to adjust the first channel.

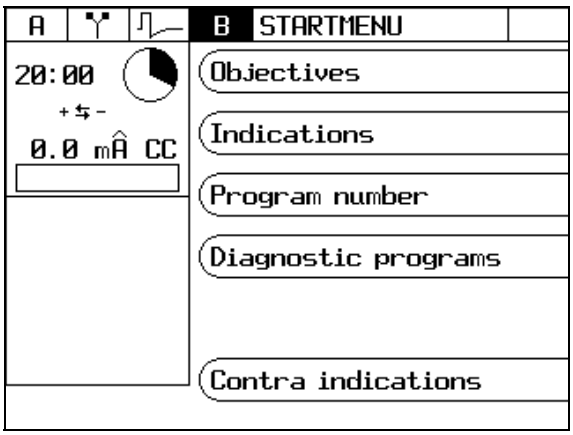
Then, by means of the Channel selection key the other channel must be selected (see below).



Select Channel B via key

If the treatment of Channel B was prepared already by means of a (former) current shape applied onto the channel B, the adjusted current shape will appear on screen.

If this is not the case (see below) the window Start menu will pop up so that the therapy mode still can be set for Channel B.



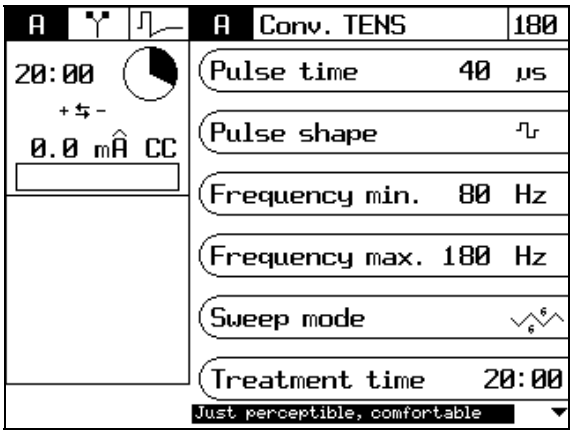
IMPORTANT:
In the other channel an other therapy mode might be selected via the selection of Electrotherapy , Ultrasound therapy, Combined therapy , Laser therapy, the Start menu or the Memory menu.

7.9 Both channels (A + B) – automatic copying of the same current shape

It is possible to set the same parameters for the second channel as they are for the settings of the first adjusted channel. In that case we recommend to switch the parameter Automatic Copying to ON in the System settings *(see chapter 10: SYSTEM SETTINGS AND BASIC SETTINGS*).

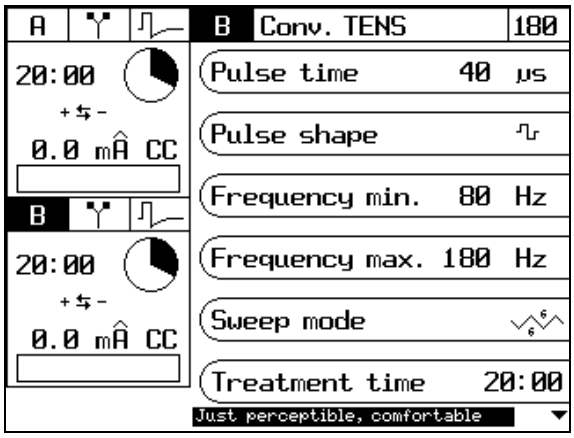
After having copied these parameters, they still can be adapted if necessary, or even another therapy method might still be selected according to the same manner as described above.

In the example (see below) a 2-pole current shape is applied to channel A.
In the System settings the option *Copy parameters to another channel* is in the ON position.



Select channel B via key

The parameters set for channel A are automatically copied in channel B (see below). Result: identical programs are set in both channels (whilst the parameters themselves can still be modified).



NOTE:

When pressing the key Channel selection and subsequently the Return key the channel window of the selected channel will be emptied.

7.10 Modify Standard programs

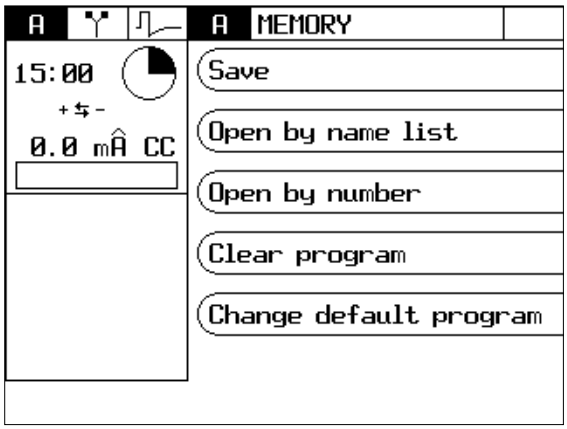
One has immediate access to the menu via the therapy keys (at the left hand side of the screen):

Electrotherapy, Ultrasound, Combined or Laser therapy.
In these menus the entire standard programs of the current shapes and the therapy methods are defined. The program number of a standard program is always smaller than 50, so that they are easy to recognize. The recommended parameter values can be modified very easily.

Attention: modifying the standard programs is only possible by means of the direct keys (at the left hand side of the screen).

The modified standard programs can be stored with the same program number, if desired so.

Permanent parameter modifications in a standard program are stored in the menu Memory by means of the Memory key (see below).



Select Change default program

A message is displayed to confirm this.

When pressing the Enter key the standard program is modified and the original program number remains in effect.

7.11 Expert Mode & Expert Times

NMES current shapes offer an option called Expert Mode. There is a certain number of particular parameter possibilities 'hidden' behind this option. They represent specialist-oriented parameters that most probably will not be set for all the treatments. After having selected the option Expert Mode, the specialist-oriented parameters are displayed on screen and they can be adjusted according to the specific preferences.

By means of the Return key one is sent back to the previous parameter screen.

Any explanation about the different parameter possibilities can simply be called while selecting the envisaged parameter and subsequently pressing the Help key ?
By means of the Return key one is sent back to the parameter screen.

We will elucidate some Expert Modes now and their functions in the paragraphs below.

7.11.1 NMES-currents – special mode

Generally speaking, NMES-currents are utilised in applications of muscle stimulation. In the case of NMES-currents, the parameter Special Mode can be adjusted via the Expert Mode. The default setting of the parameter Special Mode is the OFF position.

One can select three Special Modes with the Combi 500 unit.

7.11.1.1 Active rest (REST)

Whenever selecting the option Rest, there is still stimulation at a lower frequency (this one being adjustable) during then OFF periods. The Rest intensity is adjustable (in % of the intensity set already) as well.

Advantage: during the 'rest period' one reaches the 'muscle pumping effect'; hereby the blood circulation is activated and the patient's convalescence is stimulated.

7.11.1.2 Use of the second ON period (ON2)

As soon as ON2 is set, two independent ON periods are applied alternatively (ON and ON2).
The frequency and the intensity of both periods can be set independently (for ON2 in % of the value set for the ON-intensity).

Advantage: prevents adaptation and stimulates ‘slow twitch’ as well as ‘fast twitch’ tissue alternatively.

7.11.1.3 Frequency variation (freq ↑↓)

Whenever this parameter is selected, during the ON-time, the set frequency is automatically varied. Per ON-time, there is a diminution of 5 % until a minimum of 50 % of the originally set frequency. After that the frequency increases in steps of 5 % per ON-time until the originally set frequency is reached again. These frequency variations remain in force during the complete duration of the treatment.

Advantage: since a constant frequency leads to a relatively rapid exhaustion and diminution of the muscular activities, such a frequency variations are preventing this, thus ameliorating the healing effect of the treatment.

7.12 Alternating channels (A⇆B)

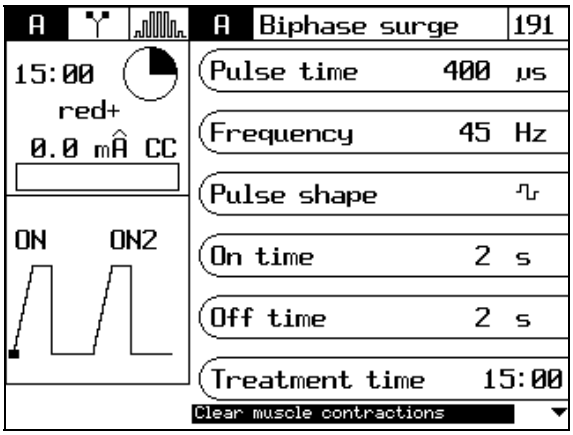
A special application of the two channel method with the help of the so called NMES burst currents, is the treatment using alternating channels, where the current is running alternatively through the channel A and the channel B.

Advantage: extremely suitable for changing stimulation of the agonistic and the anti agonistic muscle group, for instance during stabilising exercises. One can also change per extremity, for instance for alternating stimulation of the left and the right Quadriceps.

7.13 NMES-currents and 4-pole interferential currents - graphical representation of the current

In the case of NMES currents the development of these currents is represented graphically. In such a way one gets a clear picture in what phase the current is at a particular moment. That way the therapist can guide the patient in an optimal manner through the execution of the exercises.
In the event of the simultaneous application of 2 NMES currents, the current is only represented graphically on the intensity screen.

The intensity screen is reached in that case by pressing the Enter key starting at the parameter screen.



NOTE:
The evolution of the 4-pole current shapes is also graphically represented in the lower part of the channel window.

Above, one can see the dynamic representation of the NMES current shape “Biphasic Burst current”, where the special option ON2 is set.

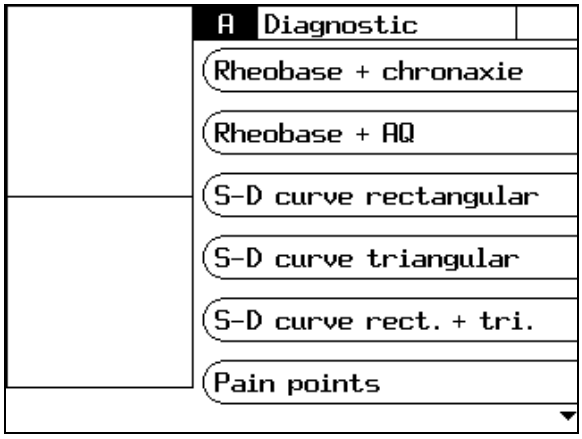
8 DIAGNOSTIC PROGRAMS

8.1 Introduction

With the help of the Combi 500 unit the therapist can find out in many different ways to what degree the electrical irritability of the neuro-muscular system is affected.
The Rheobase, the Chronaxie and the Accommodation Quotient can be measured quite rapidly.
The recording of a complete S-D curve is also possible; the graph appears on the screen and it can be stored in memory.
In addition to this the Combi 500 unit offers a number of current shapes that can be utilised to localise pain points.

NOTE:
This Chapter does not give any explanation about a number of specific topics in relation to the measuring procedures.
Refer to Chapter 6: GENERAL OPERATING INSTRUCTIONS for more information about the general operation of the Combi 500 unit.

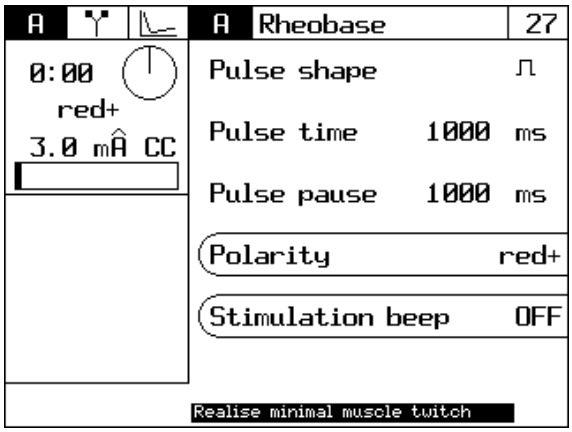
8.2 Determine Rheobase and Chronaxie



Select Rheobase + Chronaxie

While determining the Rheobase one automatically starts with a rectangular impulse of 1000 ms and an impulse pause of 1000 ms. both parameter conditions cannot be modified. The intensity is turned open (this is done in steps of 0.1 mÂ) until one detects a barely visible or sensible contraction.

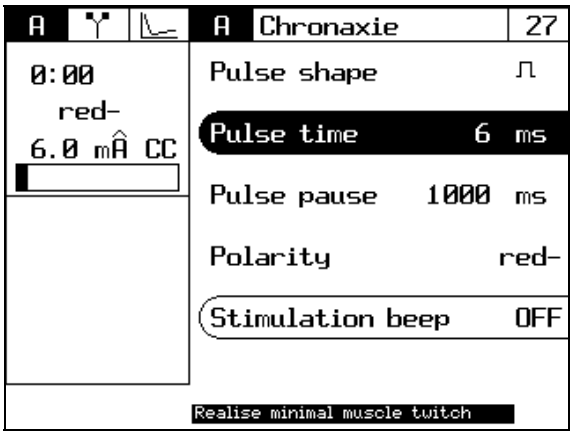
Leave the intensity regulator in that position and press the Enter key
The Combi 500 unit stores the measured Rheobase in its memory (see below).



Press the Enter key

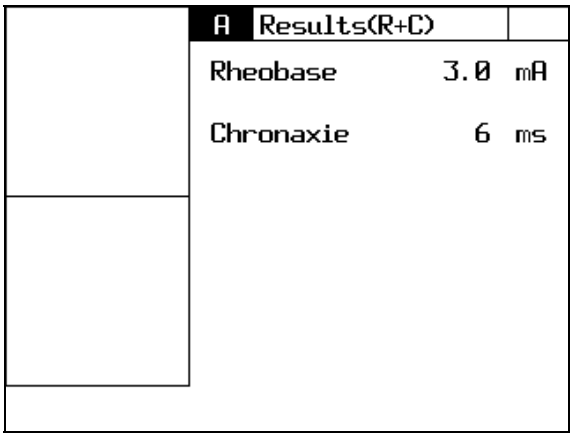
As soon as the Rheobase (in mÂ) is determined, the Combi 500 doubles the Rheobase and the parameters on screen are modified automatically to a pulse time of 0.1 ms. and a pulse pause of 1000 ms. The parameter Pulse time (see below) remains visible in the 'negative or reverse image'; one can modify these parameters with the help of the keys and

As soon as one detects a barely sensible or visible contraction, one presses the Enter key in order to memorize the measured Chronaxie (in ms.).



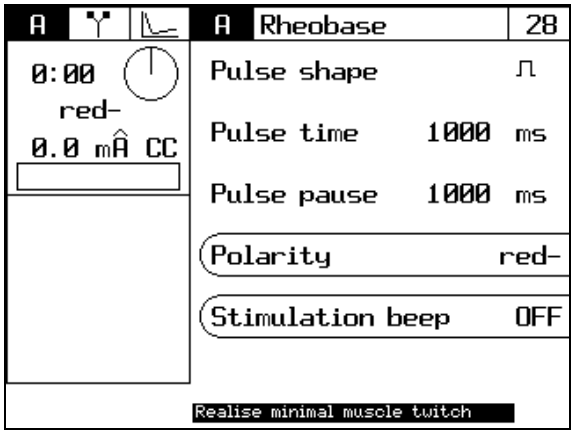
Press the Enter key

After the measurement procedure, the Result screen is displayed (see below) and these results can be stored into the memory, if so desired.



8.3 Determine Rheobase and Accommodation Quotient

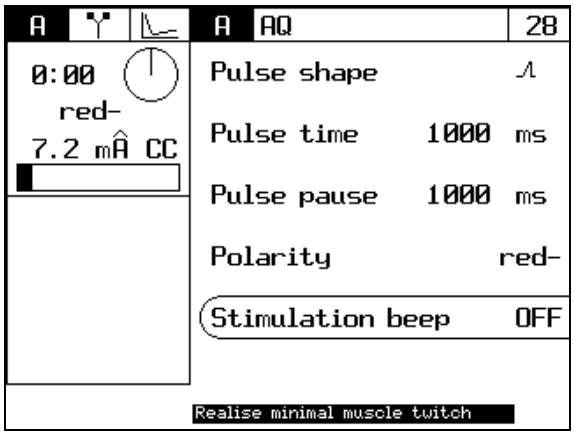
The Rheobase is determined as described in the previous paragraph.



Press the Enter key

After saving the Rheobase the Combi 500 unit automatically selects a triangular pulse of 1000 ms and a pause pulse of 1000 ms.
Now, the intensity of the channel A is turned open (this is done in steps of 0.1 mÂ) until a barely sensible or visible contraction is detected (see below).

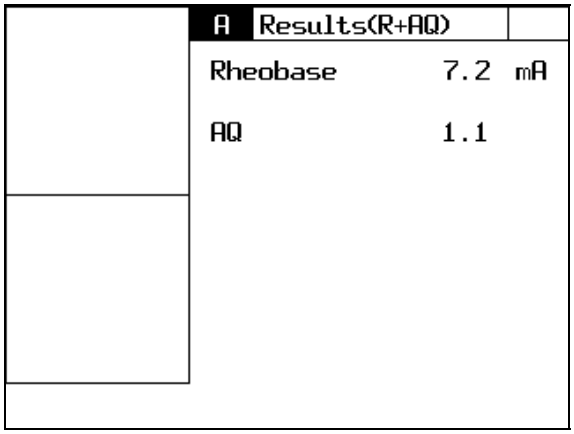
Leave the intensity regulator in this position and press the key



Press the Enter key

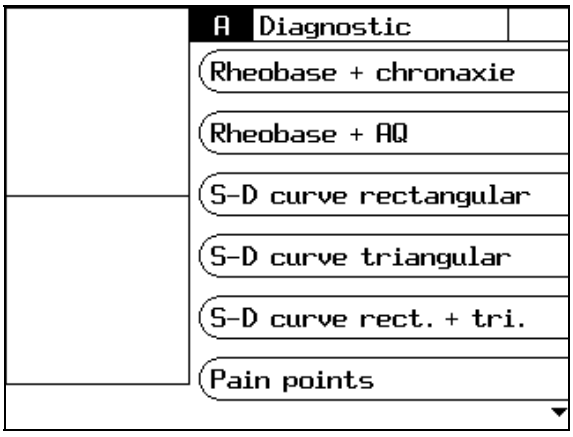
After this the Combi 500 calculates the Accommodation Quotient and displays it on the result screen (see below an example of the result window).

This result window can be stored into the memory if so desired (*see Chapter 9: TREATMENT MEMORY).*



8.4 Record S-D curve

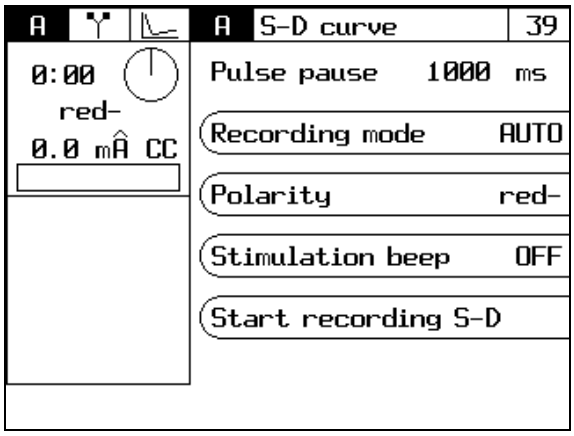
An S-D curve can be generated with a rectangular pulse, a triangular pulse or with both at the same time. The principle of the measurement is the same in the three cases.



Select S-D rectangle + triangle

After the selection of the desired measurement of the S-D curve, there is first an intermediate screen (see further), where a certain number of parameters such as the Recording mode, the Polarity and the Stimulation beep can still be modified.

If the option Recording mode is in the AUTO position, the cursor will automatically jump from the selected pulse time to the next pulse time to be measured after the measurement. If the option Recording mode is in the MANUAL position, the cursor also automatically jumps from the selected pulse time to the next pulse time to be measured after the measurement. However, under MANUAL conditions one still can choose another pulse time. In that manner one can return if there is doubt in order to repeat a specific measurement, if necessary.

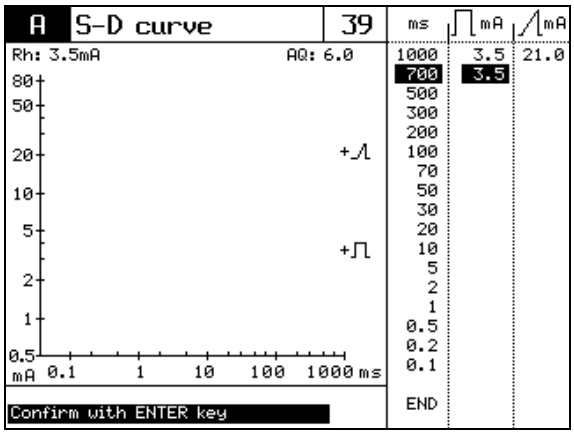


Select Start recording S-D curve

When recording the S-D curve one starts with a pulse time of 1000 ms.
After that the pulse time is decreased to the value of 0.1 ms in 17 fixed steps.
As a function of the measurement the screen also displays information about the Rheobase (Rh), the Chronaxie (Ch), the Accommodation Quotient (AQ) and the optimal pulse time (OPT).
This window is a results screen, which can be stored in the memory (*see Chapter 9: TREATMENT MEMORY*).

Every once and a while one detects a minimal contraction at a specific pulse time, one stores the relevant intensity by just pressing the Enter key (see below).

After that the same procedure must be repeated for the next pulse time.



Press the Enter key

8.4.1 S-D curve – Adjust intensity

When recording an S-D curve with nothing else than a triangular pulse, one always starts the next pulse time with an intensity of 0 mÂ,- because a shorter triangle pulse time does not always need a higher intensity.

When recording an S-D curve with nothing else than a rectangular pulse, one will need a higher intensity for a shorter pulse time. That is the reason why one always starts here with the same intensity as the one measured with the previous pulse time.

When recording a combined S-D curve, one starts at the same intensity as the one measured with the previous rectangular pulse in effect, after changing from the rectangular to the triangular pulse. When switching over from the triangular pulse to the rectangular pulse, one starts at the same intensity as the one measured with the previous rectangular pulse in effect.

8.5 Storing data in the memory

It is possible to store and save the measurements (Rheobase + Chronaxie, Accommodation Quotient, S-D-curve) in the memory under a well-determined number.
In the course of time, several curves of the same patient can be saved in order to follow up and monitor the healing process.

See Chapter 9: TREATMENT MEMORY in order to store data in the program memory.

8.6 Pain points

The Combi 500 unit offers the possibility to diagnose and treat pain points, with the help of Electrotherapy or Combined therapy (dependant on the predicted localisation of these pain points. The diagnostic program for pain points Electrotherapy is accessible from the Electrotherapy menu as well as from the Start menu. In the case of the Combined therapy the pain points programs are only accessible starting from the Start menu.

9 TREATMENT MEMORY

9.1 Introduction

The Combi 500 unit has a programmable memory that can be called via the Memory key . In this menu one can save data for later use and reference.

Often used or specific current shapes for a well-determined patient can be stored in the memory.

The transfer of treatment data to an observer is also simplified.

Together with the diagnostic programs other data (e.g. an S-D curve) can be stored.

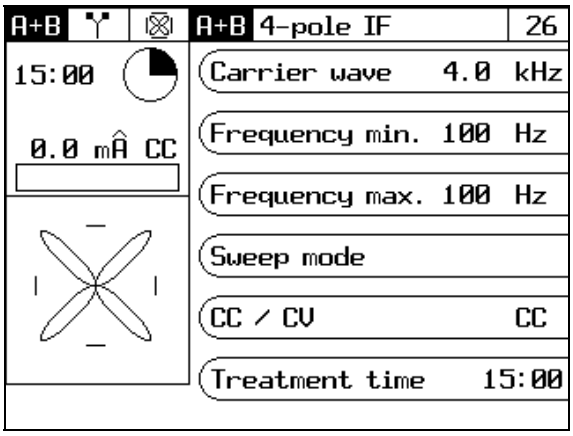
In total there are 500 memory addresses available (memory numbers 500 - 999).

All programs can be stored in an arbitrary order of succession or in other words, the available memory addresses between the numbers 500 and 999 can be arranged as one wishes.

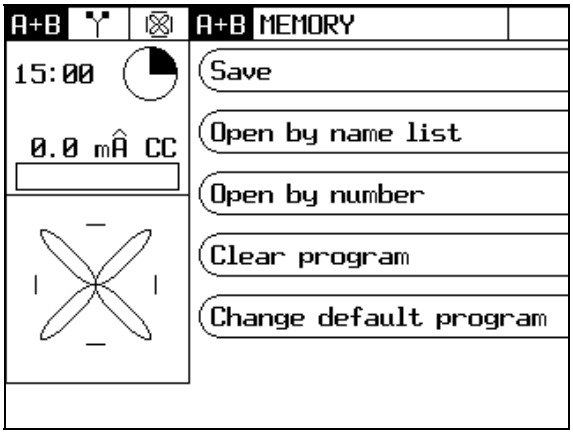
9.2 Save Therapy program / Diagnostic program

The saving of a Therapy program or of a Diagnostic program is carried out in an identical manner.

It is only possible to store a program in the memory if the intensity is at the zero level (see further) (For the programs Rheobase + Chronaxie, AQ and the S-D curves, only the result screen can be stored in the memory).



Press the Memory key

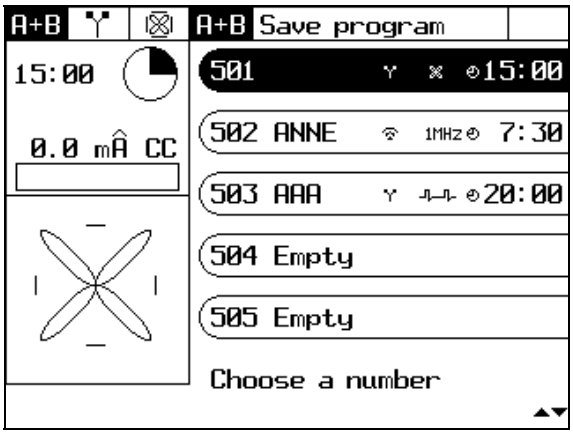


Press Save

ATTENTION:

- The selections Save and Modify standard program are two options that are not always visible in the memory display; this is indeed depending on the followed input.
- The option Save is only accessible if one selected the Memory key out of a parameter window or out of a Results window.
- The option Modify Standard program is only displayed if a standard program was selected via a direct selection of one of the therapy keys (at the left hand side of the screen). (Standard programs = program number smaller than 50).

Subsequently the program is linked automatically to the following empty number (see below number 501).



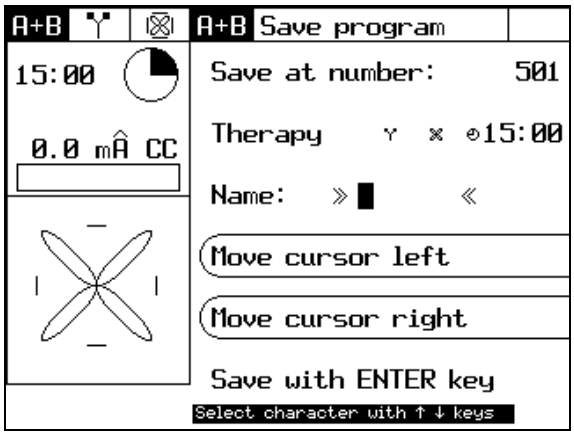
Press the Green Key next to 501 in order to save this free position

One can browse the memory list with the help of the keys and
With the relevant Green Key, one selects the number under which one wishes to save the program.
One can save items in an empty address or overwrite an already filled in address.

In the next screen (see below) one can store a name and/or a number of maximum 6 characters.

The characters are selected with the keys and . Once one detects a searched character, the cursor has to be moved to the next character in order to select that one.

Press the Enter key in order to definitely save the program.



Select the characters using the keys and

Press the Enter key

If one does not want to fill in a text, one can directly press the Enter key . The program is then saved and one leaves the Memory menu. Now, one automatically returns to the parameter screen and the treatment can start.

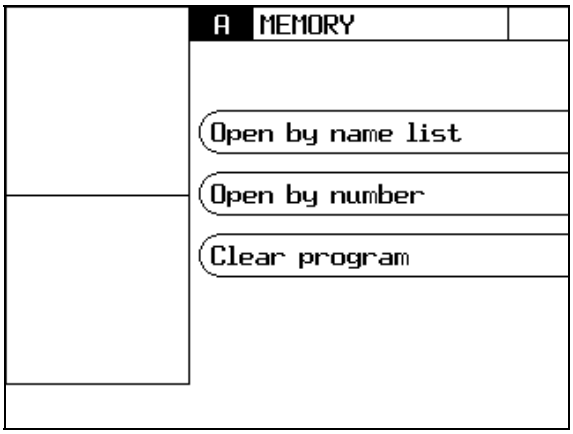
An existing program can always be overwritten. There will be a message on screen asking to confirm the selection once again. In order to confirm one has to press the appropriate Green Key again.

9.3 Open saved programs

When pressing the Treatment memory key a menu Memory is displayed and from here the stored treatment can be opened in two ways.

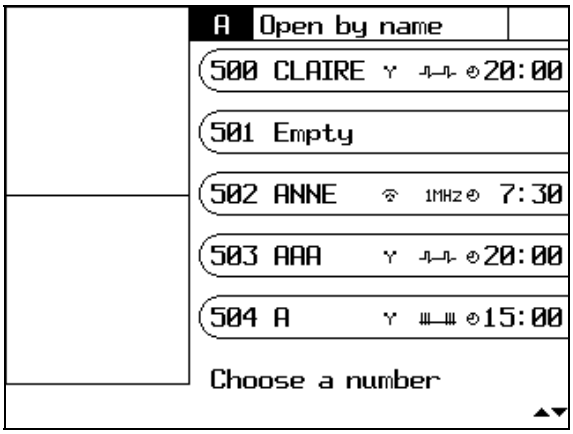
9.3.1 Opening through a list of names

The opening via the list of names (see below) displays a list with a short overview of the stored treatments together with the filled in name.



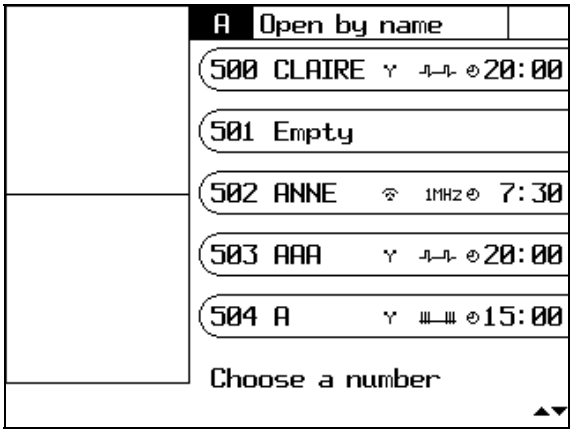
Select Open by name list

Subsequently the list with memory numbers is displayed (see below). There are 500 numbers available in total, from number 500 - 999.



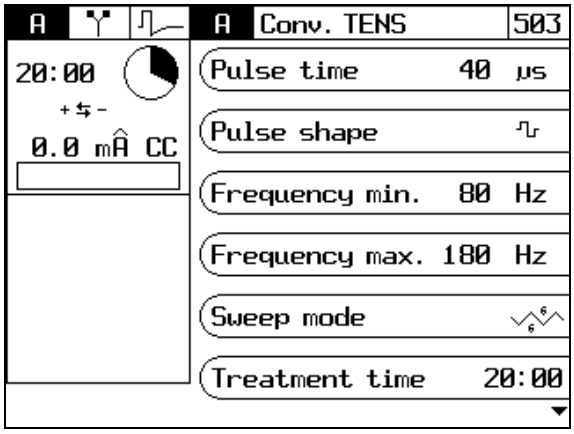
Browsing through the list with the keys ▲ *and* ▼

Once the desired number has been detected, one can simply call the treatment by pressing the relevant Green Keys.



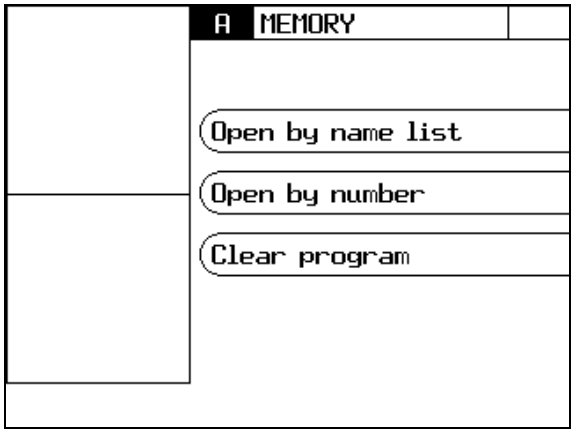
Press the Green Key 503

The treatment can start now immediately.



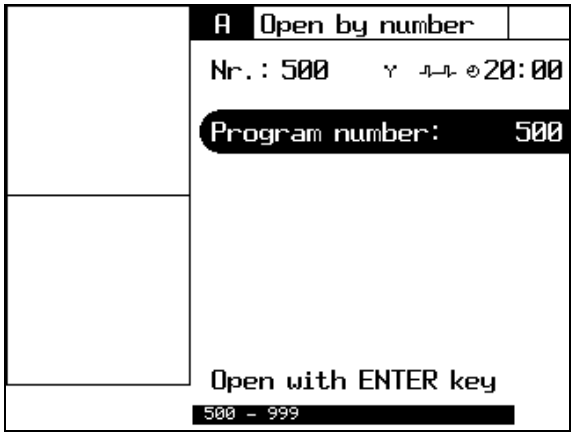
9.3.2 Opening through a number

By setting the treatment number, the treatment is directly displayed on screen.



Select Open by number

One can select the desired number with the help of the keys and



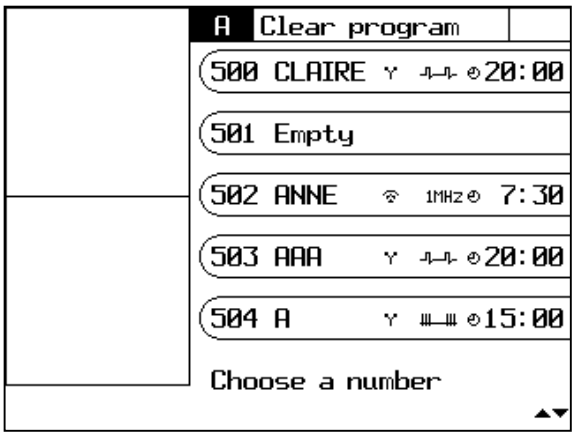
After the selection of the program number, press the Enter key and the desired treatment is displayed on screen.

9.4 Erasing data

By means of the Treatment Memory key the Treatment Memory program is displayed. From here, already stored treatments can be erased.

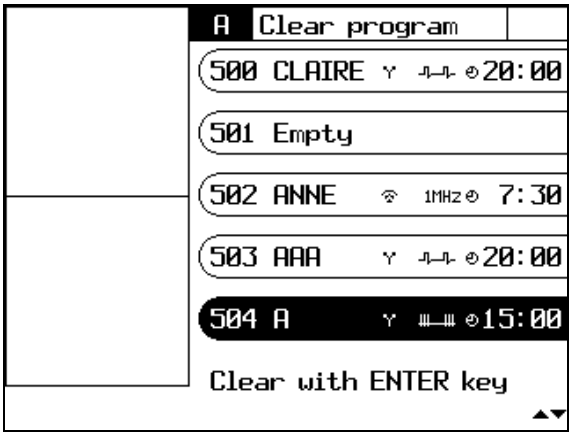
9.4.1 Erasing through list of names

See paragraph 9.3.1 for the selection of a name/number in the list.

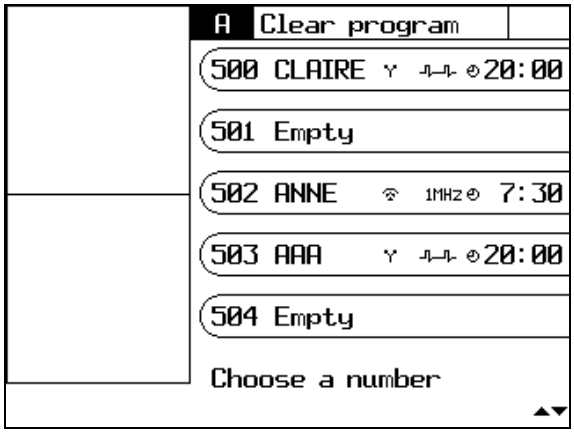


Select program 504

Press the Enter key in order to discard a program from the memory.



The list is displayed again, so that other numbers can be discarded if necessary.



Press the Enter key

With the help of the Return key one leaves the list.

10 SYSTEM SETTINGS AND BASIC SETTINGS

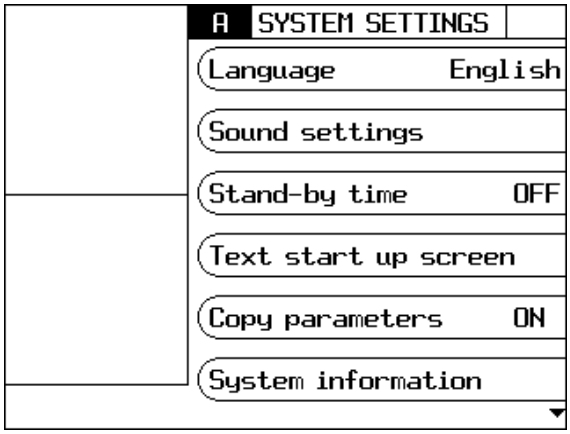
10.1 Introduction

The Combi 500 offers a number of System settings, presenting the possibility to adapt the unit in a very detailed manner to the needs of the user (customer settings).

We recommend having a thorough look at these settings before the first use of the device, and altering these settings where it is deemed necessary.

Calling up the menu System settings can be carried out as follows: in the screen Start menu the Return key must be pressed and held during 3 seconds (there may be no treatment running on both channels).

The different menu options will be described successively.



10.2 Language selection

There is a selection of 4 languages: English, German, French and Dutch *(see 3.4 for the setting of the language).*

10.3 Sound

10.3.1 Acoustic signal at the end of treatment

The acoustic signal that one can hear at the end of the set treatment time, can be switched on or off.

10.3.2 Acoustic signal when pressing a key

The acoustic signal that one can hear when pressing a key, can be switched on or off.

10.3.3 Sound during ET Stimulation

If the stimulation beep is in the ON position, the start of the stimulus can be accompanied with an acoustic signal as standard.

10.3.4 Sound volume

To adjust the volume of the acoustic signal.

10.3.5 Beep ET (Electrotherapy) contact

In order to be warned auditively in the event that there is a bad and insufficient contact between the electrode and the patient's skin, this parameter must be set to ON.

10.3.6 Beep US (Ultrasound) contact-control

In order to be warned auditively in the event that there is a bad and insufficient contact of the US head and the patient's skin, this parameter must be set to ON.

10.3.7 Beep laser power

In order to signal the laser detection of the unit.

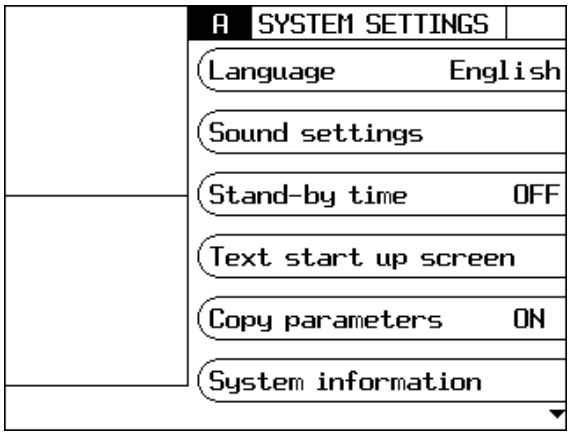
10.4 'Stand-by' time

When the Combi 500 unit is not utilised during 10 minutes, it is automatically switched into the STAND-BY position. The yellow light [35] remains illuminated. Pressing an arbitrary key will render the device operational again.

If so desired, the Stand-by time can be altered using the System settings.

10.5 Starting window text

It is possible to display one's own text data, e.g. name- or address, in the starting window. Every time the unit is switched on, these data will be displayed on the starting screen.



Select Text start up screen

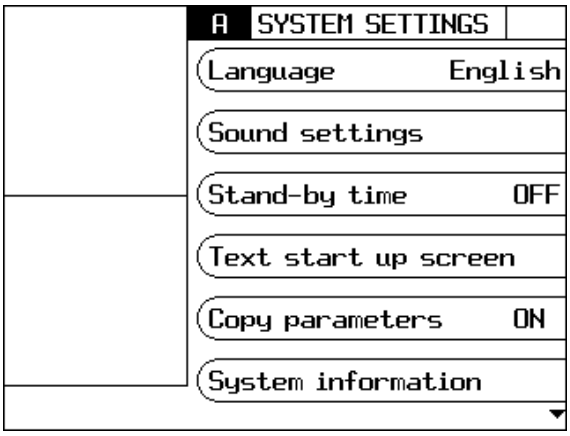
The input of the text is self-explanatory.

By means of the keys and the characters can be set and the cursor can be moved.

When the complete text is filled in, confirm it by pressing the Enter key

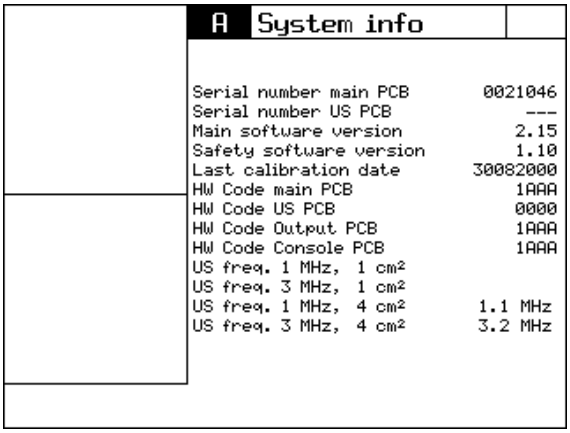
10.6 Copying parameters into another channel

If this option is active (ON) (see below), the parameters, set for the first channel, will be copied automatically whenever the second channel is selected.
If this option is not active (OFF), you will be transferred automatically to the Start screen if the second channel is selected. From the start screen one can adjust a therapy *(see also paragraph 7.8 and 7.9).*



10.7 System information

System information provides information about serial numbers, software versions, last calibration dates, hardware versions (see below).


A System info
Serial number main PCB 0021046
Serial number US PCB ---
Main software version 2.15
Safety software version 1.10
Last calibration date 30082000
HW Code main PCB 1AAA
HW Code US PCB 0000
HW Code Output PCB 1AAA
HW Code Console PCB 1AAA
US freq. 1 MHz, 1 cm²
US freq. 3 MHz, 1 cm²
US freq. 1 MHz, 4 cm² 1.1 MHz
US freq. 3 MHz, 4 cm² 3.2 MHz

Always mention the SYSTEMINFO in the event of a FAILURE WARNING to the technical services; it constitutes a great deal of GAIN OF TIME.

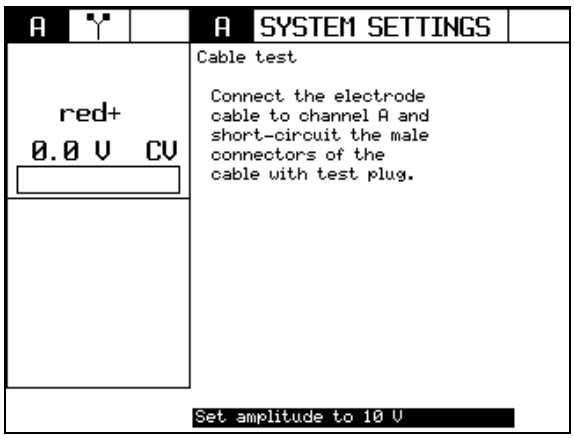
10.8 Testing Electrode cables and electrodes

Using the cable and electrode test, one can check the condition of the wiring and the electrodes.

Tip: check the wiring first, if the cables are in a good condition, proceed to the test of the electrodes.

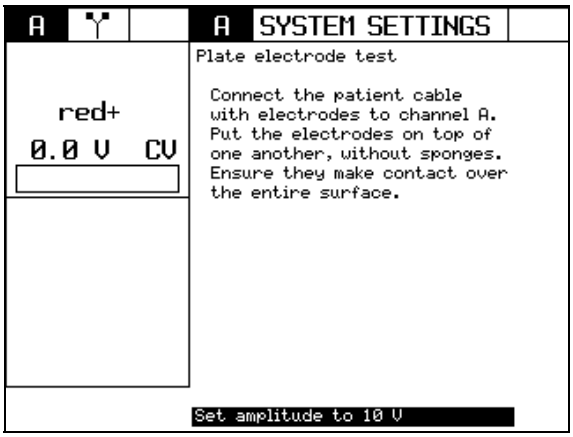
10.8.1 Testing Electrode cables

The mode of operation is clearly explained on screen.


A
A SYSTEM SETTINGS
Cable test
Connect the electrode cable to channel A and short-circuit the male connectors of the cable with test plug.
red+
0.0 V CV
Set amplitude to 10 V

10.8.2 Testing Electrodes

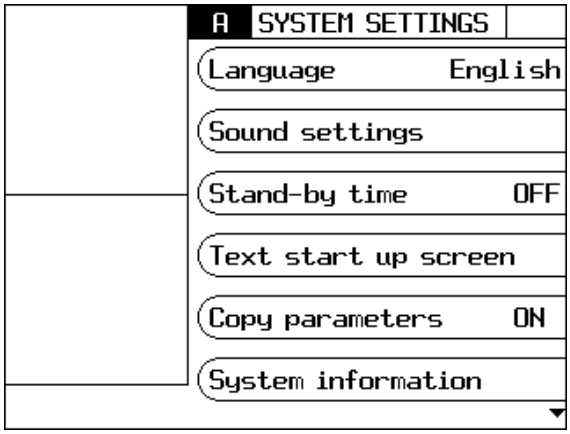
The mode of operation is clearly explained on screen.



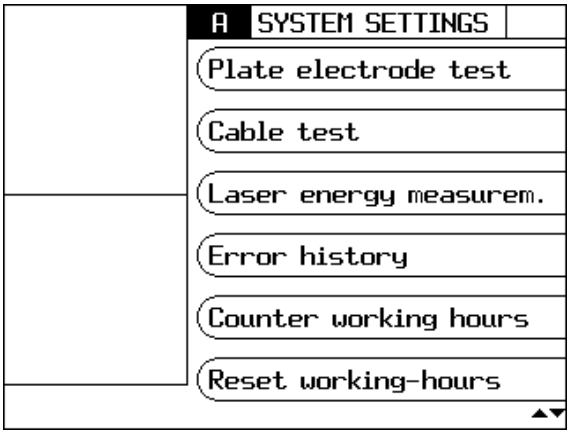
10.9 Testing Laser probes

In order to arrive at reliable measurements, it is absolutely necessary to carry out the measurement only in the case that the option Laser therapy has not yet been used on that very day.

Go to the screen System Settings

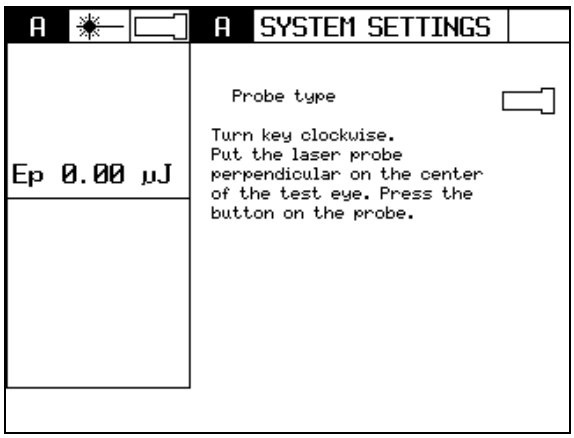


Go to the next screen



Select Laser energy measurement

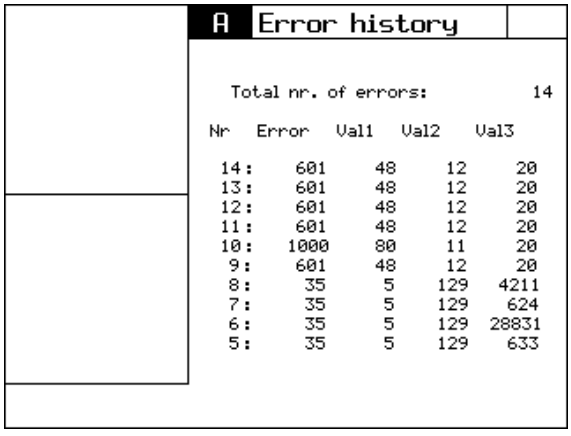
This measurement is measuring the pulse energy.



Compare the energy per pulse in the channel window with the supplied control report.
If the quadruple probe is tested, one must use yellow protection caps. In this manner one can test every individual Laser diode. Compare the sum of the four individual energy measurements with the total energy of the supplied control report.

10.10 Error history

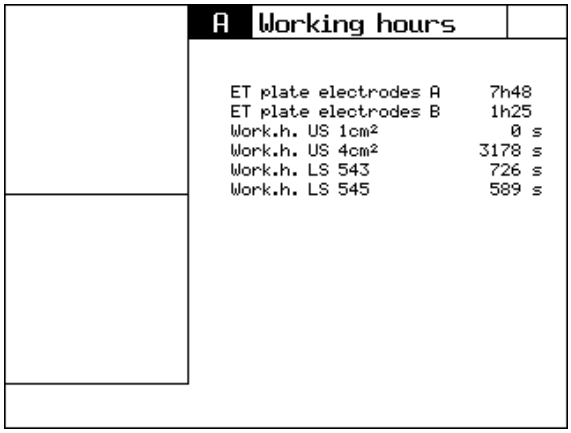
The screen ‘error history’ gives information on the total number of errors registered by your device during its lifetime. Details over the last 10 errors are also given.



In case of an error message, it is always useful to know these data. Always mention the system information in the event of a failure warning to the technical services; it constitutes a great deal of gain of time.

10.11 Working hours

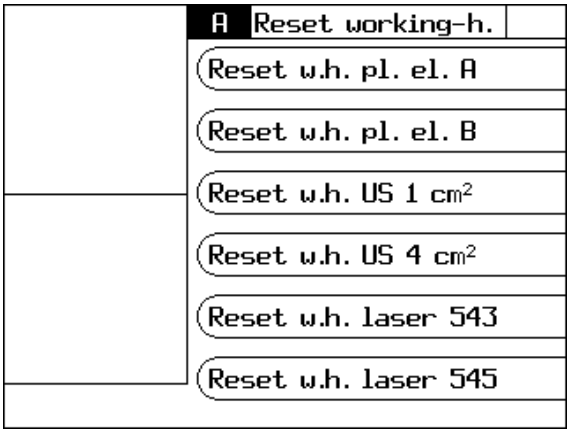
The total number of hours during which the channel for electrotherapy or ultrasound has been used will be displayed on the screen ‘working hours’. This is the time for which the amplitude of intensity of the corresponding channel has been higher than 0.


A
Working hours
ET plate electrodes A 7h48
ET plate electrodes B 1h25
Work.h. US 1cm² 0 s
Work.h. US 4cm² 3178 s
Work.h. LS 543 726 s
Work.h. LS 545 589 s

With this screen, you have information on the total number of hours the accessories have been used.

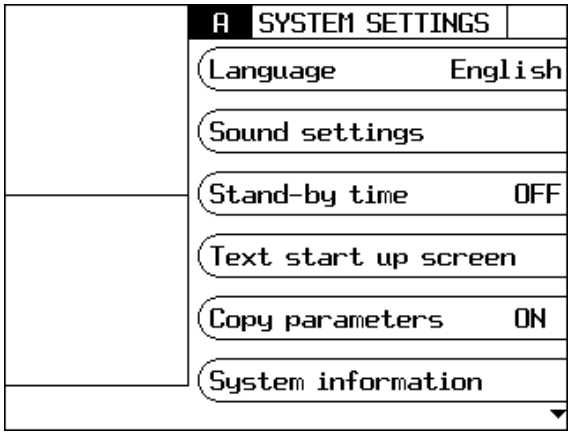
10.12 Reset working hours

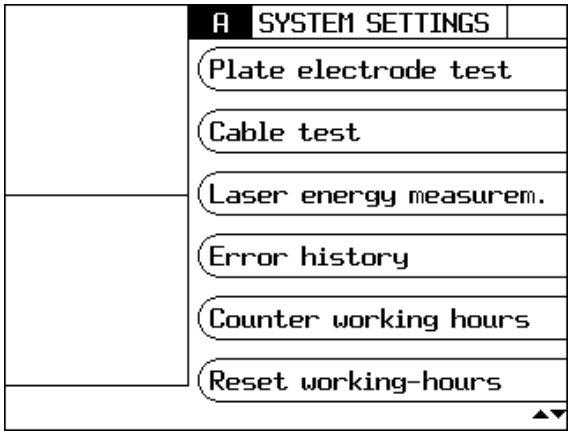
In this screen you can reset the counter for working hours. This may be useful when you bought new accessories and you want to know the total number of working hours of the accessories.

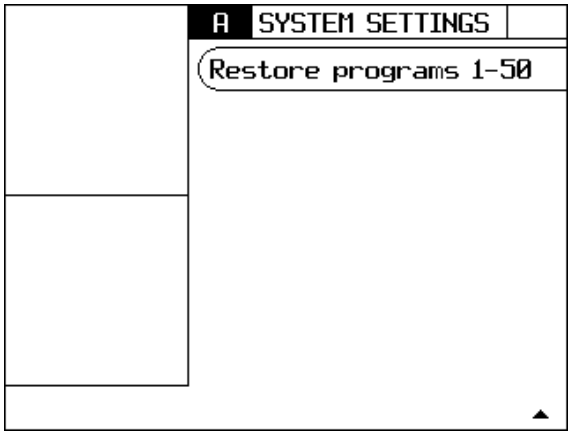


10.13 Restoring standard programs

Here the possibility exists to restore modified standard settings (default) or standard programs simultaneously to the original standard settings (see below) *(also refer to paragraph 7.10 for the standard settings)*.







Restore programs 1-50
Press once again to confirm your choice

All presettings of the modified standard programs have now been changed to their initial conditions.

NOTE:
The Standard programs are easily recognisable because of their program number between 1 and 50.

11 INDICATIONS AND CONTRA-INDICATIONS

11.1 Electrotherapy - indications

Continuous direct current
(Effect: electro-chemical effects leading to an improvement of the blood circulation, influencing the skin charge and a diminution of the pain awareness).

* Superficial circulatory disturbances.
* Neuralgia.
* Myalgia.
* Artralgia.
* Bad healing skin injuries (Ulcus cruris, Decubitus).
* Bad healing injuries of the soft parts of the bone (chronic tendon lesions, fractures).
* As an introducing treatment for electro stimulation (improvement of the electrical irritability).
* As a current shape to apply iontophoresis.

Pulsated rectangular and triangular current
(Effect: in most of the applications monophasic pulses are applied; so see: continuous direct current effects, further: generation of action potentials at the membrane of the nerve fibres).

* See: indication for the continuous direct current.
* As current shape for diagnosis in order to detect what the condition is of the peripheral motor neuron.
* As electro stimulation in the case of peripheral paresis.
* As electro stimulation for smooth muscular tissue in the event of constipation.

2-5 current - Ultra Reiz current
(Effect: diminution of the pain awareness, improvement of the blood circulation, and detonisation of the muscular tonus).

* Artrosis Deformans (especially the knee joint, the ankle joint).
* Hypertoni.
* Myalgia.
* Chronic a-specific pain situations (lumbar pain and thoracic spine).
* Neuralgia.
* Circulatory disturbances.
* Vegetative disturbances.

Intermediate frequency rectangular current
(Effect: see the effects of the continuous direct current).

* See the indications in the case of continuous direct current.
* As current shape to apply iontophoresis (advantage: less probability for skin irritation).

Diadynamic currents

(Effect: improvement of the blood circulation locally superficial as well as intra-muscular, diminution of the pain awareness, detonisation of the muscular tonus).

* Posttraumatic diseases.
* Rheumatic diseases.
* Superficial circulatory disturbances.
* Artralgia (posttraumatic, degenerative).
* Neuralgia.
* As current shape in order to apply a segmental therapy.
* As current shape to detect segmental deregulations (through the examination of the dermatomes).

TENS current shapes

(Effect: diminution of the pain awareness, improvement of the local, segmental and central blood circulation, detonisation of the muscular tonus, normalisation of the sympathetic reflex activity).

* Acute and chronic pain (pain in the lower back, headaches, pain in the neck, dysmenorrhoea, pain in the arms, pain in the legs, phantom pain).
* Arthralgia (posttraumatic, degenerative, rheumatic).
* Circulatory disturbances.
* Post-surgical pains.
* Neuralgia.
* Myalgia.
* Posttraumatic dystrophy (Südeck dystrophy, sympathetic reflex dystrophy).
* Active myofascial trigger points.
* Actual segmental deregulations.
* Disturbed sympathetic reflex activity.
* Urgency incontinence.
* As current shape to look for active specific stimulus points.

NMES current shapes with low-frequent current

(Effect: improvement of the neuromuscular functions such as the absolute muscular strength, stamina (endurance), explosive muscular strength, improvement of the activity daily life (ADL) functions, improvement muscle awareness, decrease spasticity).

* Atrophy or imminent atrophy.
* Decreased muscular stamina (endurance).
* Decreased function of the pelvic floor muscles (stress-incontinence for urine and/or faeces).
* Spasticity Cardio-vascular diseases, MS, injuries central nerve system, spinal cord lesion and paraplegia.
* Circulatory disturbances.
* Oedema interstitial tissue.
* Cellulites.
* Loss of muscle awareness, disturbed locomotive image.
* As current shape to improve the activity daily life (ADL): functional electro stimulation (FES) to improve walking (peroneus stimulator) or stretching.

NMES current shapes with intermediate-frequency current

(Effect: improvement of the neuromuscular functions such as the absolute muscular strength, stamina (endurance), explosive muscular strength, improvement of the activity daily life (ADL) functions, improvement muscle awareness, decrease).

* Atrophy or imminent atrophy.
* Decreased muscular stamina (endurance).
* Decreased function of the pelvic floor muscles (stress-incontinence for urine and/or faeces).
* Spasticity Cardio-vascular diseases, MS, injuries central nerve system, spinal cord lesion and paraplegia.
* Circulatory disturbances.
* Loss of muscle awareness, disturbed locomotive image. Atrophy or imminent atrophy.

Intermediate-frequency electrotherapy applied by means of interference

(Effect: decreased pain awareness, improvement blood circulation, detonisation of the muscular tonus, normalisation of the sympathetic reflex activity).

* Acute and chronic pain (pain in the lower back, headaches, pain in the neck, dysmenorrhoea, pain in the arms, pain in the legs, phantom pain).
* Arthralgia (posttraumatic, degenerative, rheumatic).
* Blood circulation disturbances.
* Post-surgical pains.
* Neuralgia.
* Myalgia.
* Posttraumatic dystrophy (Südeck dystrophy, sympathetic reflex dystrophy).
* Active myofascial trigger points.
* Actual segmental deregulations.
* Disturbed sympathetic reflex activity.
* Urgency incontinence.
* As current shape to look for active specific stimulus points.

Iontophoresis indications

* Arthralgia.
* Arthritis.
* Superficial calcium deposits in soft parts (myositis ossificans, bursitis calcarea, tendinitis calcarea).
* Superficial connective tissue contractures.
* Decubitus, ulcus cruris.
* Oedema.
* Tendon lesions (tennis elbow, golfer elbow, m. Quervain, shin splints, lesions Achilles tendon, plantar fasciitis, insertion tendinopathia supraspinatus, adductors, quadriceps-tendon).
* Fungal infections.
* Gouty arthritis.
* Hyperhydrosis.
* Herpetic Whitlow (felon).
* Myalgia.
* Active myofascial trigger points.
* Neuralgia.
* Rheumatic diseases.
* Scars adhesions.
* Viral infections.

11.2 Ultrasound therapy - indications

* Arthrosis.
* Bechterew.
* Bursitis.
* Contractures.
* Decubitus.
* Distortion.
* Dupuytren.
* Epicondylitis.
* Fractures.
* Frozen shoulder.
* Myalgia.
* Neuropathy.
* Posttraumatic diseases.
* Tendonitis.
* Ulcus Cruris.

11.3 Combined therapy - indications

* Arthrosis.
* Contractures.
* Distortion.
* Epicondylitis.
* Myofascial pain points.
* Neuropathies.
* Tendonitis.

11.4 Laser therapy - indications

* Arthritis.
* Bursitis.
* Cellulites.
* Decubitus.
* Distortion.
* Epicondylitis.
* Herpes simplex.
* Myalgia.
* Myofascial pain points.
* Neuralgia.
* Posttraumatic diseases.
* Quervain.
* Rheumatoid arthritis.
* Scars problems.
* Tendonitis.
* Ulcus Cruris.

11.5 Electrotherapy - contra-indications

There are three sorts of contra-indications:
- General contra-indications: valid for all treatment methods;
- Specific, absolute contra-indications: a specific treatment method cannot be applied;
- specific, relative contra-indications: a specific treatment method may not be applied on specific spots or with a specific dose.

11.5.1 Electrotherapy monophasic pulses / iontophoresis - contra-indications

General contra-indications:
* Severe fever.
* Serious cardio-vascular problems.
* Psychological problems (patient's resistance, serious excitement).
* Cancer, tumours (metastasis).
* General TB tuberculosis.

Specific, absolute contra-indications:
* On demand pacemaker.

Specific, relative contra-indications:
* Skin diseases.
* Skin infections.
* Thrombosis , thromboflebitis.
* Varicose.
* Increased probability of bleedings.
* Superficially implanted materials.
* Heart diseases with rhythm disorders (for thoracic applications).
* Decreased sensibility.
* Around sinus caroticus (deregulation of the nervus vagus).
* Menstruation (during the first days abdominal and lumbar).
* Pregnancy (during the first days abdominal and lumbar).

11.5.2 Electrotherapy biphasic pulses - contra-indications

General contra-indications:
* Severe fever.
* Serious cardio-vascular problems.
* Psychological problems (patient's resistance, serious excitement).
* Cancer, tumours (metastasis).
* General TB tuberculosis.

Specific, absolute contra-indications:
* On demand pacemaker.

Specific, relative contra-indications:
* Skin infections.
* Thrombosis, thromboflebitis.
* Heart diseases with rhythm disorders (for thoracic applications).
* Decreased sensibility.
* Around sinus caroticus (deregulation of the nervus vagus).
* Pregnancy (during the first days abdominal and lumbar).

11.6 Ultrasound therapy - contra-indications

General contra-indications:
* Severe fever.
* Serious cardio-vascular problems.
* Psychological problems (patient's resistance, serious excitement).
* Cancer, tumours (metastasis).
* General TB tuberculosis.

Specific, absolute contra-indications for continuous ultrasound**:**
* Infections.
* Acute inflammations.
* Thrombosis, thromboflebitis.
* Varicose.
* Increased tendency for bleeding.
* Pacemaker.
* Epiphysarial disk (children).
* Decreased sensibility.
* Menstruation.
* Cement for endoprothesis.
* Diabetis mellitus.

Specific, relative contra-indication for pulsating ultrasound:
* Pacemaker.
* Pregnancy.

11.7 Combined therapy - contra-indications

Refer to Electrotherapy and Ultrasound therapy

11.8 Laser therapy - contra-indications

General contra-indications:

* Severe fever.
* Serious cardio-vascular problems.
* Psychological problems (patient's resistance, serious excitement).
* Cancer, tumours (metastasis).
* General TB tuberculosis.

Specific, absolute contra-indication:

* Looking into the laser beam.
* Thyroid gland (local applications).
* Increased connective tissue production.
* Hypertrophic scars tissue.
* Pregnancy.
* Photo-allergy.

12 INTERFERENCES, WARRANTY, LIABILITY, SERVICE

12.1 Interferences

A MISTAKE HAS BEEN MADE WHILE OPERATING THE UNIT.
Information is displayed on screen about what exactly is going on. One can repair the failure oneself by following the instructions on screen.

IT IS IMPOSSIBLE TO SWITCH ON THE COMBI 500 UNIT when pressing one of the keys. In this case the yellow warning light ⏻ is not illuminated.
Check if the mains voltage is present, if the main switch is in the ON position, if the mains voltage cable is in good condition and finally if no fuses have blown. If the main fuses have blown, one can replace them by intact ones. Take the power cable out of the mains voltage wall plug and pull the fuse holder out of the mains voltage switch, if necessary with the aid of a screwdriver, in order to replace the fuses. Make sure you use the appropriate fuses that come with the unit exclusively. It is possible to order these fuses at your local Gymna dealer (type as mentioned on the sticker, affixed next to the mains voltage switch). If it is still impossible to switch on the Combi 500 unit after having replaced the fuses, please contact the repair services of your local Gymna dealer.

THE COMBI 500 UNIT DOES NOT REACT TO THE COMMANDS OF THE CONTROLS and an error message is displayed on screen.
The protective device of the Combi 500 unit has detected an error. It is impossible to continue the operations. In most of the cases an instruction will be displayed on the screen. Detach the links to the patient and switch off the unit by means of the mains voltage switch. Wait for a while and switch back on the appliance. If the error is recurrent, please contact the repair services of your local Gymna dealer.

There is a FOREIGN LANGUAGE on screen.
Set the desired and appropriate language via the menu System settings. If the error is recurrent, please contact the repair services of your local Gymna dealer.

After having switched on the device, ERROR MESSAGE appears on the display. Turn off the device and switch it back on. Please contact the repair services of your local Gymna dealer, if the error is recurrent.

12.2 Warranty and Liability

12.2.1 Guarantee conditions

The guarantee period for the COMBI 500 is 1 (one) year, counting from the purchase date (the date on the purchase invoice counts as evidence). This guarantee covers all defects in material and workmanship.

The above-mentioned one-year guarantee does not apply in case of repairs of failures or defects caused by:

- injudicious use of the device;
- an incorrect interpretation of or failure to comply with the directions in this Operating Instructions;
- negligence or accidents;
- maintenance or repairs by persons not authorised thereto by the manufacturer.

12.2.2 Liability

The manufacturer cannot be held liable for any consequences, either for the therapist, or for the patient, or for the equipment used, of, for example:

- an incorrect diagnosis;
- improper use of the device or any of its accessories;
- misinterpretation or disregard of the user manual;
- bad maintenance of the device;
- maintenance and/or repairs of the device carried out by persons not authorised thereto by the manufacturer.

Neither the manufacturer, nor your local Gymna supplier can in any way whatsoever be held liable, in the event of transfer of infections via the probes or the electrodes.

12.3 Service

GymnaUniphy declares that he is responsible for the proper functioning only when:

- all repairs, modifications, extensions or adjustments have been carried out by persons authorised thereto;
- the electric installation of the relevant room satisfies the applicable statutory regulations;
- the device is used by authorised persons according to the instructions in this Operating Instructions;
- the device is used for the purpose for which it has been designed;
- the maintenance of the device is carried out regularly and in the manner prescribed;
- *See also paragraph 2.7: Technical Control*;
- the statutory regulations relating to the use of the device are complied with.

With the exception of the fuses in the mains input there are no components in the device that can be replaced by the user. Improper use or failure to maintain the device according to the regulations shall release GymnaUniphy and its representatives from all liability for any damage, injuries, defects or malfunctioning arising there from.

Service and guarantee will be provided via your Gymna supplier.

The terms of delivery of your Gymna supplier shall apply.

The guarantee shall lapse when the device is not used in accordance with the above points.

The expected lifetime of the device is 10 years.

Ten years after having put the Combi 500 device (or any of its accessories) into circulation, the manufacturer of the device cannot be held liable anymore for not supplying spare parts or accessories.

13 MAINTENANCE AND CLEANING

Before carrying out any maintenance or repair work on the Thermo 500, the device must be disconnected from the electricity network.

13.1 Cleaning the device

For the normal everyday maintenance of the device or its accessories, it does not need to be opened.

If necessary, you can clean the outside of the device with a dry or slightly moistened cloth.

We strongly advise against the use of any solvent whatsoever, as this may harm the materials used.

In case of persistent stains a non-aggressive soap solution may be used.

Make sure in any case that no moisture can get into the device or the accessories! Carefully dry all parts.

In order to continue to guarantee the quality and the safety requirements of the device, it is not permitted for unauthorised persons to open the device or its accessories for any reason whatsoever.
The opening of the device or any of its accessories (for maintenance or repair), is reserved for recognised qualified professionals authorised thereto by the firm of GymnaUniphy*.*

13.2 Cleaning electrodes and sponges

The electrodes must be cleaned thoroughly after every use in a non-aggressive soap solution. Carefully rinse and dry.

The sponges must be rinsed out thoroughly in clear water after every treatment.
If so desired one can add a splash of vinegar (to prevent and remove possible calcium depositions); in such a case rinse the sponges once again in clear water.

Electrodes, sponges and fixating bandages may also be cleaned in a 70% alcohol solution. The use of an other disinfectant might also be envisaged. The accessories coming into contact with the patient's body must be washed in clear water after having been disinfected. This has to be done to prevent any allergic reaction

The sponges can also be washed in boiling water during one minute and subsequently be soaked through in a saline solution in order to improve the conducting characteristics. Before immersing the sponges in boiling water, they have to be soaked in water already.

13.3 Cleaning the incontinence treatment probes

BECAUSE OF THE VERY PERSONAL AND INTIMATE CHARACTER OF THE TREATMENTS IT IS STRONGLY RECOMMENDED TO LET EVERY PATIENT PURCHASE HIS/HER OWN PROBE AND TO USE THIS PROBE IN A STRICTLY RESERVED PERSONAL MANNER !

All used probes must be cleaned and disinfected very thoroughly after every treatment. This can be done in the following way :

Immediately after the treatment:
- put the probe in a 70% alcohol solution for at least 30 minutes;
- subsequently the probe is washed thoroughly in water and soap (or in a non-aggressive detergent);
- put the probe (wiring included) during 20 minutes in a HAC*-solution of 1 % (see also the instructions leaflet inside the HAC-packaging). Attention: the connector of the probe is not in stainless steel and should therefore be kept out of the HAC-solution;
- after 20 minutes the probe can be taken out of the HAC-solution, dried with a clean towel and stowed away (for instance in a clean, dry, plastic box).

** HAC : Hospital Antiseptic Concentrate*

Immediately before the use of the probe:
- clean and wash it once again very thoroughly in water and soap;
- the application of a layer of an antiseptic lubricating jelly to the probe is then recommended;
- another possibility is the use of the on the market available 'ready for use' disinfecting products; for the correct use and application of these products it is recommended, though, to read the supplied information leaflet carefully.

NOTE:
The use of an autoclave sterilizer (a disinfecting device primarily used in hospitals) is not possible because of the important heat.

Opening the probes (for maintenance and repair purposes) is reserved to qualified personnel authorised thereto by the firm of GymnaUniphy*.*

13.4 Cleaning the Ultrasound head

US heads can be cleaned using a soft moisturized cloth. If so desired, one can clean and disinfect the treatment surface with the help of a cotton bud Q-tip, soaked in a 10 % HAC*-solution. Always rinse well after that in clear water.

** HAC : Hospital Antiseptic Concentrate*

13.5 Cleaning Laser probes

Laser probes can be cleaned using a soft moisturized cloth. If so desired, one can clean and disinfect the probes with the help of a cotton bud Q-tip, soaked in a 10 % HAC*-solution.

** HAC : Hospital Antiseptic Concentrate*

14 SPECIFICATIONS

14.1 Rectified currents

Programs:
* Direct Current (DC)
* Intermediate Frequency rectangular current

Parameters:

- Polarity	red+, red-
- Sort of Current	CC
- Intensity	0 - 80 mÂ at 300 to 1000 Ω
- Channels	A or B, or both

Programs:
* Iontophoresis Intermediate Frequency rectangular current
* Iontophoresis direct current

Parameters:

- Electrode-surface	6 - 300 cm²
- Polarity	red+, red-
- Sort of Current	CC
- Intensity	0 - 80 mÂ at 300 to 1000 Ω
- Channels	A or B, or both

Programs:
* Interrupted rectangular current
* Interrupted triangular current
* 2-5 Current (Ultra Reiz)

Parameters:

- Pulse time	0,1 ms - 6 s
- Pulse pause	1 ms - 6 s
- Polarity	red+, red-, alternating
- Stimulation beep	on / of
- Sort of Current	CC / CV
- Intensity CC	0 - 80 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

14.2 Diadynamic currents

Programs:
* MF
* RS
* DF
* CP
* LP

Parameters:

- Polarity	red+, red-, 1/2 time polarity switching
- Stimulation beep	on / off
- Sort of Current	CC / CV
- Intensity CC	0 - 80 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both
- ISO	on / off (on: during MF period, intensity automatically 12,5% less than set)

14.3 TENS currents

Programs:
* Conventional TENS
* Low frequency TENS
* Brief intense TENS

Parameters:

- Pulse time	10 - 900 µs
- Pulse shape	symmetrical, asymmetrical
- Frequency min.	1 - 500 Hz
- Frequency max.	1 - 500 Hz
- Polarity	red+, red-, alternating
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

Program:
* Random frequency Tens

Parameters:

- Pulse time	10 - 900 µs
- Pulse shape	symmetrical, asymmetrical
- Pulse frequency	1 - 500 Hz, with automatic random frequency hopping of maximum +/- 35%
- Polarity	red+, red-, alternating
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 V peak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

Program:
* Burst Tens

Parameters:

- Pulse time	10 - 900 µs
- Pulse shape	symmetrical, asymmetrical
- Pulse frequency	20 - 500 Hz
- Burst-frequency	1 - 10 Hz
- Polarity	red+, red-, alternating
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

14.4 NMES currents

Programs:
* Rectangular surge current
* Triangular surge current

Parameters:

- Pulse time	0,1 - 5 ms
- Pulse frequency	1 - 150 Hz
- On2 frequency	1 - 150 Hz
- Rest frequency	1 - 150 Hz
- Polarity	red+, red-, alternating
- Stimulation beep	on / off
- Expert parameters	
- Sort of Current	CC / CV
- Intensity CC	0 - 80 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

Program:
* Biphasic surge current

Parameters:

- Pulse time	10 - 900 µs
- Pulse frequency	1 - 500 Hz
- On2 frequency	1 - 500 Hz
- Rest frequency	1 - 500 Hz
- Pulse shape	symmetrical, asymmetrical
- Polarity	red+, red-, alternating
- Stimulation beep	on/off
- Expert parameters	
- Sort of Current	CC / CV
- Intensity CC	0 - 80 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

Program:
* Biphasic surge intrapulse interval

Parameters:

- Pulse time	10 - 900 µs, with a constant interval between positive and negative pulse of 100 µs
- Pulse frequency	1 - 500 Hz
- On2 frequency	1 - 500 Hz
- Rest frequency	1 - 500 Hz
- Polarity	red+, red-, alternating
- Stimulation beep	on / off
- Expert parameters	
- Sort of Current	CC / CV
- Intensity CC	0 - 80 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 80 mÂ
- Channels	A or B, or both

Program:
* 2-pole interferential surge current

Parameters:

- Carrier wave frequency	2 - 10 kHz
- AM frequency	1 - 200 Hz
- On2 frequency	1 - 200 Hz
- Rest frequency	1 - 200 Hz
- Stimulation beep	on / off
- Expert parameters	
- Sort of Current	CC / CV
- Intensity CC	0 - 80 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 14OmÂ
- Channels	A or B, or both

Program:
* Russian stimulation

Parameters:

- Carrier wave frequency	2 - 10 kHz
- Burst frequency	20 - 100 Hz
- On2 frequency	20 - 100 Hz
- Rest frequency	20 - 100 Hz
- Stimulation beep	on / off
- Expert parameters	
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 14OmÂ
- Channels	A or B

Program:
* 4-pole interferential surge current

Parameters:

- Carrier wave frequency	2 - 10 kHz
- AM frequency	1 - 200 Hz
- On2 frequency	1 - 200 Hz
- Rest frequency	1 - 200 Hz
- Stimulation beep	on / off
- Expert parameters	
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 14OmÂ
- Channels	A or B

Expert parameters NMES currents:

- Serial duration (ON)	1 - 100 s
- Serial pause (OFF)	0 - 100 s
- Active Rest (REST)	0 - 100 s
- Surge time	0 - 100 s
- Hold time	calculated automatically
- Shrinking time	0 - 100 s
- Rest hold time	calculated automatically
- Special settings	ON2, REST, FREQUENCY VARIATION
- Alternating channels	on / off (not for 4-pole interferential surge current)
- On2 intensity	1 - 100%
- Rest intensity	1 - 100%

14.5 Interferential currents

Program:
* 2-pole interferential current

Parameters:

- Carrier wave frequency	2 - 10 kHz
- AM Frequency min.	0 - 200 Hz
- AM Frequency max.	0 - 400 Hz
- Frequency hopping mode	0/1/0, 1/5/1, 6/0/6, 12/0/12 (surge time / hold time / shrink time in s)
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 14OmÂ
- Channels	A or B, or both

Program:
* 4-pole interferential current

Parameters:

- Carrier wave frequency	2 - 10 kHz
- AM Frequency min.	1 - 200 Hz
- AM Frequency max.	1 - 400 Hz
- Frequency hopping mode	0/1/0, 1/5/1, 6/0/6, 12/0/12 (surge time / hold time / shrink time in s)
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 14OmÂ
- Channels	A and B

Program:
* 4-pole interferential with rotating vector

Parameters:

- Carrier wave frequency	2 - 10 kHz
- Pulse time	calculated automatically
- AM Frequency min.	0 - 200 Hz
- AM Frequency max.	0 - 400 Hz
- Frequency hopping mode	0/1/0, 1/5/1, 6/0/6, 12/0/12 (surge time / hold time / shrink time in s)
- Rotation	auto / manual
- Rotation time	0 - 20 s
- Rotation angle	0 - 355 °
- Sort of Current	CC / CV
- Intensity CC	0 - 140 mÂ at 300 to 1000 Ω
- Intensity CV	0 - 140 Vpeak open terminal voltage, if short-circuited maximum current 14OmÂ
- Channels	A and B
- Expert parameters	
- Segment angle	0 - ± 30 °
- Segment time	0 - 10 s

14.6 Diagnostic programs

Programs:
* Rheobase and Chronaxie
* Rheobase and Accommodation Quotient
* S-D curve rectangle
* S-D curve triangle
* S-D curve rectangle and triangle

General parameters:

- Polarity	red+, red-
- Stimulation beep	on / off
- Sort of Current	CC
- Intensity	0 - 80 mÂ at 300 to 1000 Ω (rheobase-calculation 40 mÂ)
- Channels	A or B

Parameters determination Rheobase:

- Pulse shape	rectangular pulse
- Pulse time	1000 ms
- Pulse pause	1000 ms

Parameters determination Chronaxie:

- Pulse shape	rectangular pulse
- Pulse time	0,1 - 100 ms
- Pulse pause	1000 ms

Parameters determination Accommodation Quotient:

- Pulse shape	rectangular pulse, triangular pulse
- Pulse time	1000 ms
- Pulse pause	1000 ms

Parameters C-D curves:

- Pulse time	0,1 - 1000 ms
- Pulse pause	1000 ms
- Measuring method	automatic, manual

Note
For Constant Current:
- variation of the load impedance within the defined limits has barely no influence at all

For Constant Voltage:
- at decreasing load impedance, the current increases.
- without load, the terminal voltage is equal to 140 Vpeak.
- in the case of short-circuit, the output current will be in AC 140 mA_{piek} and in DC 80 mA_{piek}.

14.7 Generalities

Memory addresses: 500 - 999
Languages: English, German, French, and Dutch
Treatment time: 0 - 60 minutes
Help function to explain the selected parameter or the current shape
2 independent channels with the possibility to adjust different therapy methods per channel
Extensive list of indications for the recommended therapy programs
Sequential therapy methods
Possibility to set the various system settings and the program parameters according to the personal preferences.
Build in cable and electrode test
Robust metal frame (Faraday cage)

14.8 Ultrasound therapy

Generalities

Frequencies Ultrasound	: 1 and 3 MHz
Duty cycles	: 10%, 20%, 30%, 40%, 50%, 100%
Pulse frequency	: 100 Hz
Peak intensity	: 0-2 W/cm² - duty cycle 100%
	: 0-3 W/cm² - duty cycle < 100%
Treatment time	: 0-30 minutes

Ulltrasound (US) head: model 591

ERA	: 0,6 cm² at 1 MHz
	: 1,0 cm² at 3 MHz
BNR	: < 5
Wave type	: divergent at 1 MHz
	: collimating at 3 MHz

Ultrasound head: model 592

ERA	: 4,0 cm² at 1 MHz
	: 4,8 cm² at 3 MHz
BNR	: < 8
Wave type	: collimating

14.9 Combined therapy

Electrotherapy:

Conventional TENS	: see electrotherapy
Low frequency TENS	: see electrotherapy
Burst TENS	: see electrotherapy
Random frequency TENS	: see electrotherapy
Brief intense TENS	: see electrotherapy
2-pole interferential	: see electrotherapy

Ultrasound therapy : see ultrasound therapy

14.10 Laser therapy

Generalities

Safety class	: 3B laser product
Wave length	: 904 nm

Monoprobe : model 543

Number of laser diodes	: 1
Nominal ocular risk distance	: 214 mm
Energy per pulse	: 2,35 µJ
Peak performance	: 13,5 W
Max. average power	: 70,5 mW
Pulse frequency	: 2-30000 Hz
Pulse time at 50 % of the peak power	: 155 ns
Beam surface near laser opening	: 12,9 mm²
Beam divergence	: Dual modes 10 ° and 45 °

Quadruple probe: model 545

Number of laser diodes	: 4
Total energy per pulse	: 10,8 µJ
Peak performance	: 4 x 18 W
Max. average power	: 54 mW
Pulse frequency	: 2-50000 Hz
Pulse time at 50 % of the peak power	: 145 ns
Beam surface near laser opening	: 4x5,3 mm²
Beam divergence	: Dual modes 7° and 21° per beam

15 TECHNICAL SPECIFICATIONS

(Technical modifications reserved)

15.1 Appliance

Mains voltages	: 110,115,127,220,230, 240 Vac / 50/60 Hz
Allowed tolerance mains voltage	: +/- 10%
Maximum power - in operation	: 96 VA
Mains voltage fuses	: 2 x T 2 A / 250 V
Dimensions (w x h x d)	: 450 x 125 x 320 mm
Weight	: ca. 8 kg
Construction year	: see label [30] at the backside of the unit.
Manufacturer	: GymnaUniphy®
Head office	: Pasweg 6 A B - 3740 BILZEN Tel. +(32)(0)89-510.510 Fax. +(32)(0)89-510.511 E-Mail : info@gymna-uniphy.com Website : www.gymna-uniphy.com

REMARK

Always give the SYSTEMINFO to the technical services as soon as possible in the event of a FAILURE REPORT; this means a substantial GAIN OF TIME.

To do that, one can proceed as follows:

Press the Start menu key if there is no treatment in progress on both channels.
Subsequently, press and hold the Return key for 3 seconds.
One enters thus in the menu System settings.
In this screen one can select the relevant System information.

15.2 Specifications safety

15.2.1 Appliance

Safety class	: II - type BF II: the unit is equipped with a ground protection and must be plugged into a wall plug with a grounding; BF: the appliance is equipped with a floating patient circuitry.
Current limitation	: 140 mA peak for alternating currents 80 mA peak for rectified currents
Hardware current limitation	: 150% compared to the set value and 110% of the maximum value of the selected current shape
Measured value + accuracy	: output current in milliAmpère – typical +/- 10% output power in Watt - typical +/- 20%

15.2.2 Ultrasound heads

Frequencies Ultrasound	: 1 and 3 MHz
Pulse frequency	: 100 Hz
Peak intensity	: 0-2 W/cm² - duty cycle 100%
	: 0-3 W/cm² - duty cycle < 100%
Ultrasound head: model 591	
ERA	: 0,6 cm² at 1 MHz
	: 1,0 cm² at 3 MHz
BNR	: < 5
Wave type	: divergent at 1 MHz
	: collimating at 3 MHz
Ultrasound head: model 592	
ERA	: 4,0 cm² at 1 MHz
	: 4,8 cm² at 3 MHz
BNR	: < 8
Wave type	: collimating

15.2.3 Laser probe

Safety class : 3B laser product
Generated wave lengthy : 904 nm

Monoprobe : model 543

Number of laser diodes	: 1
Energy per pulse	: 2,35 µJ
Peak performance	: 13,5 Watt
Max. average power	: 70,5 mWatt
Pulse frequency	: 2-30000 Hz
Pulse time at 50 % of the max. power	: 155 ns
Beam surface nearby laser opening	: 12,9 mm²
Beam divergence	: Dual modes 10 ° and 45 °

Quadruple probe: model 545

Number of laser diodes	: 4
Total energy per pulse	: 10,8 µJ
Peak performance	: 4 x 18 Watt
Max. average power	: 54 m Watt
Pulse frequency	: 2-5000 Hz
Pulse time at 50 % of max. power	: 145 ns
Beam surface near laser opening	: 4 x 5,3 mm²
Beam divergence	: Dual modes 7 °and 21 ° per beam

16 ACCESSORIES

16.1 Standard accessories

Quantity	Description	Article number
2	Two wired electrode cable	108725
2	Rubber electrode nr. 2 - 6 x 8 cm (per 2 pc.)	109959
1	Chamex-sachet nr. 2 for electr. 6 x 8 cm (per 4 pc.)	100658
2	Elastic fixation bandage - 5 x 30 cm	108934
2	Elastic fixation bandage - 5 x 60 cm	108935
2	Elastic fixation bandage - 5 x 120 cm	108936
4	Adaptor cable - 4 > 2 mm	113334
1	Adhering electrode - 5 x 5 cm (per 4 pc.)	101795
1	Stimulation-electrode with sponges	109943
1	Multifrequent US head 1/3 MHz- ERA 4 cm² incl. holder	114858
1	Contact Gel - 150 ml	100018
1	Mains voltage cable	100689
1	Test plug V/V - 4mm	108919
1	Treatment Guide	114855

16.2 Optional accessories

Description	Article number
Electrotherapy:	
Vaginal stimulation probe with 6-pole DIN	107348
Anal stimulation probe with 6-pole DIN	107349
Rectal stimulation probe	112166
Rubber electrode nr. 1 - 4 x 6 cm (per 2 pc.)	109958
Rubber electrode nr. 3 - 8 x 12 cm (per 2 pc.)	109960
Chamex-sachet nr. 1 for electr. 4 x 6 cm (per 4 pc.)	100657
Chamex-sachet nr. 3 for electr. 8 x 12 cm (per 4 pc.)	100659
Adhering electrode, round - diam. 3 cm (per 4 pc.)	113335
Adhering electrode - 3,8 x 5 cm (per 4 pc.)	107858
Adhering electrode - 5 x 10 cm (per 4 pc.)	107860
Sponges for stimulation-electrode (per 10 pc.)	109944

Recommendation:
We recommend the replacement of the electrode-material at least every 6 months.

Ultrasound:	
Multifrequent US head 1/3 MHz- ERA 1 cm² incl. holder	114857
Contact Gel - 500 ml	100016
Contact Gel - 5 l	100019
Pump for 5 l - canister	100020
Laser:	
Monoprobe - model 543 incl. holder and 2 laser spectacles	114859
Quadruple probe - model 545 incl. holder and 2 laser spectacles	114860
Laser protection glasses	111890

17 EXPLANATION OF THE SYMBOLS

17.1 Symbols at the front side of the appliance

Up / Down

Stop

Pause

Return

Enter

Start menu

Electrotherapy

Combined therapy

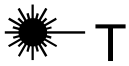
Memory

Help

Ultrasound

Laser

Channel A/B

Laser test 

Stand-by

Intensity channel A

Intensity channel B

Read Operating Instructions first

17.2 Symbols on the side and back of the appliance

Output channel A for electrotherapy

Output channel B for electrotherapy

BF: the appliance has a floating patient circuitry

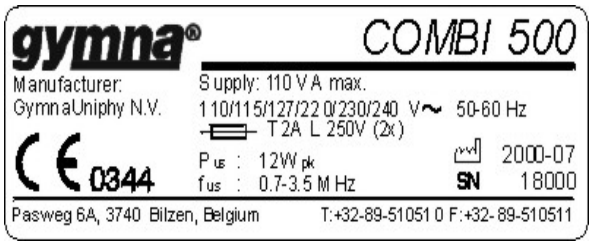
Connection for laser probe

Contact laser function

Connection multifrequent US head

Sensible to Electrostatic Discharges

Sample label Combi 500 unit with technical data:



Serial input and output

17.3 General symbols

Electrotherapy	
Sequential current shapes	SEQ
Iontophoresis	
Channel A	A
Channel B	B
Alternating channels	A⇆B
Channel A+B	A+B
Treatment time	

17.4 Symbols groups of current shapes

4-pole interferential	
2-pole interferential	
TENS currents	
Uni-directional currents	
NMES-currents	
Diadynamic currents	
S-D curves, Rheobase / Chronaxie / AQ	

17.5 Symbols current shapes

Direct current	
Iontophoresis	
Intermediate frequent rectified current	
Direct current interrupted, rectangular current	
Direct current interrupted, triangular current	
TENS continuous	
TENS low frequency	

Brief intense TENS	
TENS random	
TENS burst	
Rectangular surge current	
Triangular surge current	
Biphasic surge current	
Biphasic surge current intrapulse interval	
2-pole interferential surge current	
Russian stimulation	
4-pole interferential surge current	
MF (Diadynamic)	MF
RS (Diadynamic)	RS
DF (Diadynamic)	DF
CP (Diadynamic)	CP
LP (Diadynamic)	LP
2-pole interferential	
4-pole interferential	
4-pole interferential with rotating vector	
Rheobase and Chronaxie	CH
Rheobase and Accommodation Quotient	AQ
S-D curve rectangular pulse	S-D
S-D curve triangular pulse	S-D
S-D curve rectangular and triangular pulse	S-D

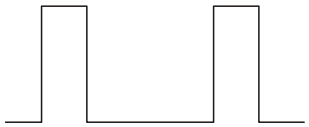
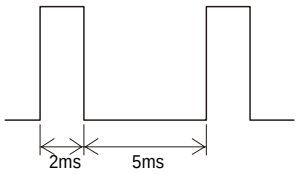
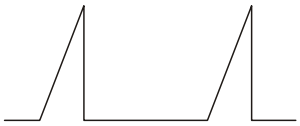
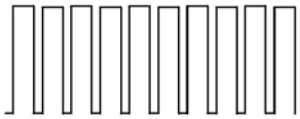
17.6 Parameter symbols

Polarity indication	red -, red +
Alternating polarity	
Biphasic pulse shape symmetrical	
Biphasic pulse shape asymmetrical	
Frequency sweep modes: 12s/12s	
6s/6s	
1s/5s - 1s/5s	
1s/1s	
Rest frequency	REST
Second ON-time	ON2
Frequency hopping	
Alternating channels	
Rectangular pulse	
Triangular pulse	
Constant Current	CC
Constant Voltage	CV
mA peak	
Volt	
Monoprobe	
Quadruple probe	
Symbol Laser test	
US duty cycle 10%	10%
US duty cycle 20%	20%
US duty cycle 30%	30%
US duty cycle 40%	40%
US duty cycle 50%	50%

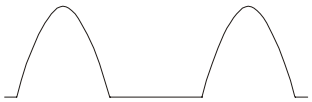
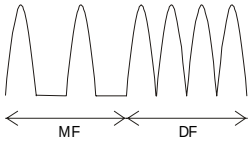
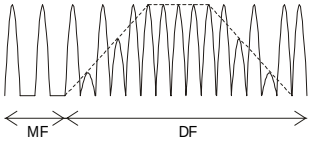
US duty cycle 100% (continuous)	⌐¯¯ 100%
Set US intensity	$\hat{I}_{set}$
Nominal peak US output power	P_{pk}
Unit of the set US intensity	W/cm²
Set average Laser power	$\bar{P}_{set}$
Total administered Laser energy Of the current treatment	E_{tot}

17.7 Drawings of the current shapes

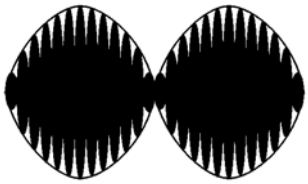
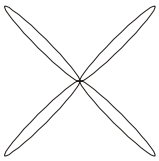
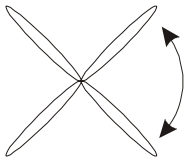
Unidirectional Currents

		
Direct current	Rectangular pulse	2-5 current (Ultra Reiz)
		
Triangular	Medium frequency rectangular	

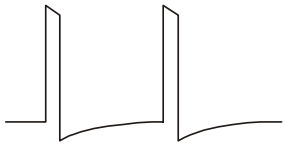
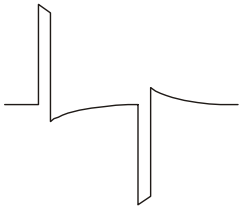
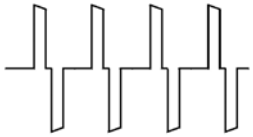
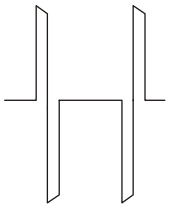
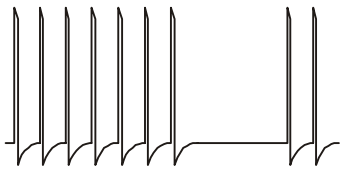
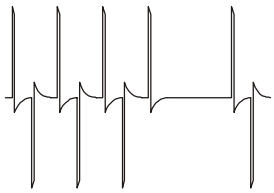
Diadynamic Currents

		
MF	RS	DF
		
CP	LP	

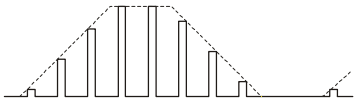
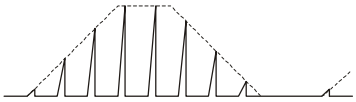
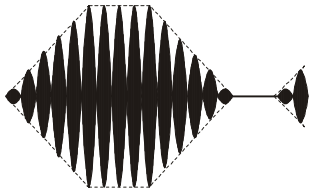
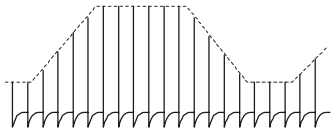
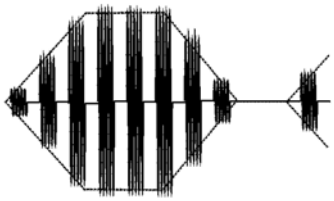
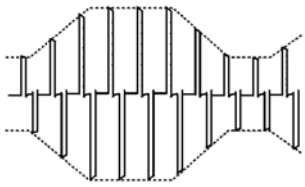
Interferential Currents

		
2-pole Interferential	4-pole Interferential	4-pole Interferential with rotating vector

Tens Currents

 Conventional Tens a-symmetrical	 Conventional Tens Alternating a-symmetrical	 Conventional Tens symmetrical
 Conventional Tens Alternating symmetrical	 Tens-burst	 Tens Burst alternating

NMES Currents

 Rectangular Surge	 Triangular Surge	 Medium Frequency Surge
 Tens Surge	 Russian Stimulation	 Intrapulse Interval Surge

For more information about the different current shapes and parameters: consult the Help key ?

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